THE UNIVERSITY *of* EDINBURGH

Policy and Practice Concerning Women with an RhD negative Blood Type:

A midwifery perspective

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Declaration

I declare that this thesis was composed by me, Mairi Harkness, and that the work is my own. The work has not been submitted for any other degree or professional qualification.

Signed……

Date:…….

Abstract

In May 2002 the National Institute for Clinical Excellence (NICE) made the recommendation that all pregnant women with an RhD negative blood type should be offered routine antenatal anti-D immunoglobulin (Ig) prophylaxis (RAADP). Midwives were the key professional group who would be involved in administration of anti-D Ig and yet they had little input to formation of policy and contributed little to the evidence base that informs policy and practice. A midwifery perspective is however important and relevant, and forms the basis of this work.

The thesis comprises three distinct, but related, pieces of research: a survey conducted in 2005 to determine implementation of RAADP at UK maternity units; secondary analysis of anti-D Ig errors involving midwives that were reported to the Serious Hazards of Transfusion (SHOT) scheme in 2007/8; and focus group interviews conducted in 2010 to explore midwives' views on issues that impact the care provided for women with an RhD negative blood type.

The aim of the RAADP survey was to establish current {2005} policy in the United Kingdom in relation to the NICE recommendation for RAADP (NICE, 2002). The survey formed the foundation on which to build the thesis by determining that by 2005 RAADP had become an integral aspect of maternity care within the UK. However it also found that there were significant variations within local policies and among the information that was provided to pregnant women and healthcare professionals. The aim of the survey was to determine implementation of policy and not to explain findings, raising important questions which were used to inform the subsequent research.

The second piece of research was secondary analysis of existing anti-D Ig error reports collated by SHOT. The analysis was unique in that it included only those errors involving midwives. The findings highlight both individual and organisational impact on errors, building on the findings of the RAADP survey. The research identified proximal errors, trigger events and fallible practices providing a framework within which the common pathways to error involving anti-D Ig can be

understood. This will allow midwives to better understand and improve the care they provide. This piece of research also raised further questions about midwifery practice and those questions informed the focus group research.

The focus group research aimed to consolidate the findings of the previous research by gaining direct input from midwives. Two focus group interviews were held, with clinical midwives as participants. The research found that the midwives and the organisations within which they worked provided care in line with policy and procedure at the apparent expense of a woman centred approach. This appeared to be linked to the midwives' understanding of their responsibility, accountability and the education and information that underpinned the care they provided. The other important finding from the focus group research was that the midwives regarded RAADP as a less important intervention than they did anti-D Ig given following a potentially sensitising event (PSE) during pregnancy or given following delivery.

When considered as a whole body of work, this research provides unique and valuable insight to midwifery involvement in the care of women with an RhD negative blood type. The research highlights the challenge of achieving government objectives for individualised, woman centred care within the present framework of clinical governance and evidence based care. In doing so it also raises questions about how individual midwives and the midwifery profession have engaged with medical colleagues and policy makers to maintain a midwifery context to the care they provide. Although the research findings relate to care provided for women with an RhD negative blood type the findings are pertinent to other aspects midwifery practice, particularly those originating within the medical profession that are now a routine part of midwifery care.

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List of Abbreviations

BTS:	Blood Transfusion Service
FMH:	Feto Maternal Haemorrhage
HDFN:	Haemolytic Disease of the Fetus and Newborn
NHS:	National Health Service
NICE:	National Institute for Clinical Excellence
NMC:	Nursing and Midwifery Council
PSE:	Potentially Sensitising Event
RAADP:	Routine Antenatal Anti-D Prophylaxis
RCM:	Royal College of Midwives
RCOG:	Royal College of Obstetricians and Gynaecologists
RhD:	Rhesus D
RhD HDFN:	Rhesus D Haemolytic Disease of the Fetus and Newborn
SHOT:	Serious Hazards of Transfusion
SNBTS:	Scottish National Blood Transfusion Service
UK:	United Kingdom
UKCC:	United Kingdom Central Council for Nursing, Midwifery and Health Visiting

Glossary of Terms

Antigen
A substance that, when introduced into the circulation of a person lacking that antigen, can stimulate production of a specific antibody.

Antibody (ies)
A plasma protein produced as the result of the introduction of a foreign antigen. Antibodies have the ability to combine with, and sometimes destroy, the cells carrying the antigen that stimulated their production.

Anti-D antibody (ies)
The antibody produced as a result of exposure to the RhD antigen. Anti-D antibodies can combine with and destroy red blood cells carrying the RhD antigen.

Anti-D Immunoglobulin (Ig)
A blood product containing a high concentration of anti-D antibodies. It is manufactured from the blood of human donors.

DATIX
Patient safety software used to record and report healthcare incidents and errors.

Feto-maternal Haemorrhage (FMH)
Transfer of fetal blood into the maternal circulation.

Flow Cytometery
A laser-based laboratory technology that is used to count specific cells: for example to count the amount of fetal haemoglobin in a maternal blood sample.

Haemolytic Disease of the Fetus and Newborn (HDFN)
An alloimmune condition that develops in a fetus and/or newborn. It occurs when antibodies produced by the mother pass through the placenta into fetal circulation causing fetal red blood cells to break down. HDFN can cause anaemia, and ranges from very mild to severe. Fetal or neonatal death is rare but can occur.

Immune anti-D
Anti-D antibodies produced by a person in response to exposure to the RhD antigen, as opposed to anti-D present as a result of injection of anti-D immunoglobulin (passive anti-D).

Immunisation, *also known as* **Sensitisation**
A process by which an individual's immune system produces antibodies against a specific antigen. Immunisation is permanent and irreversible.

Index pregnancy
In this work it refers to the pregnancy during which a woman becomes immunised or sensitised.

Glossary of Terms

Kleihauer Test
A laboratory test that measures the amount of fetal haemoglobin present in a maternal blood sample.

Maternal sensitisation
Production of red cell antibodies by a mother as a result of exposure to an antigen from her fetus during a pregnancy.

Passive anti-D
Anti-D antibodies present in a person's blood as a result of receiving an injection of anti-D immunoglobulin, as opposed to anti-D antibodies produced in response to exposure to the RhD antigen (immune anti-D).

Potentially Sensitising Event (PSE)
An event that is thought to increase the risk of feto-maternal haemorrhage and subsequent maternal sensitisation: for example, vaginal bleeding and invasive uterine procedures.

Rhesus (Rh)
Refers to the Rhesus blood group system, consisting of around 50 blood group antigens including D, C, c and E.

Rhesus D (RhD)
Refers to the D antigen, one of the antigens of the Rhesus blood group system

Rhesus D (RhD) negative
Refers to absence of the RhD antigen: RhD negative blood does not contain the RhD antigen.

Rhesus D positive
Refers to presence of the RhD antigen: RhD positive blood contains the RhD antigen.

Routine Antenatal Anti-D Prophylaxis (RAADP)
Anti-D immunoglobulin offered routinely during pregnancy regardless of any potentially sensitising event. It should be administered during the third trimester, with the aim of preventing silent sensitisation.

Sensitisation, also known as **Immunisation**
A process by which an individual's immune system produces antibodies against a specific antigen. Sensitisation is permanent and irreversible.

Silent Sensitisation
Maternal sensitisation that occurs in the absence of any apparent potentially sensitising event.

Chapter 1: Introduction

1.1 Introduction

In May 2002 the National Institute for Clinical Excellence (NICE) made a recommendation that all pregnant women with an RhD negative blood type should be offered routine antenatal prophylaxis with anti-D immunoglobulin (RAADP) (NICE, 2002). The recommendation was controversial and constituted a significant change from current practice. Anti-D immunoglobulin (Ig) is a blood product and its use in clinical practice is controlled by the blood transfusion services of the United Kingdom (UK). When this work was commenced the researcher was employed as a Transfusion Specialist Midwife with the Scottish National Blood Transfusion Service, a role which involved facilitating the safe and effective use of blood and blood products, including anti-D Ig, through education, research and clinical effectiveness initiatives. The then new NICE guidance inspired the researcher to consider the care offered to pregnant women with an RhD negative blood type. In particular the impression that although midwives were the key professional group involved in administration of anti-D Ig, they appeared to have had little or no input in the formation of policy and had contributed little published evidence to inform practice. A midwifery perspective on this subject is relevant and important and forms the foundation of this research. The research was completed part time, and developed through and alongside the researcher's clinical work. This created challenges but also opportunities that might not otherwise have been available. The resulting work forms this thesis, a body of work that was also clinically relevant within the researcher's role as a transfusion specialist midwife.

The work comprises three distinct pieces of research: A survey of all UK maternity units to establish policy surrounding provision of RAADP; secondary analysis of midwifery errors involving anti-D Ig as reported to the Serious Hazards of Transfusion (SHOT) report and focus group interviews to explore midwives' perspective on the care provided for RhD negative women. These three separate pieces of research, when considered together, give a broad perspective on current

practice and the contribution that midwives make to the care provided for pregnant and postnatal women with an RhD negative blood type.

The work started in 2004, with the RAADP survey completed in 2005. A request was received from a member of the NICE RAADP review group to use data from the RAADP survey (Appendix 2) and it was subsequently referred to in the 2008 review (NICE, 2008, Pg7). In 2008 the research was published in the Journal of Transfusion Medicine (Harkness et al, 2008 (Appendix 1)). The work is presented here as a concise chapter with a summary of the main findings. Completion of the RAADP survey research was followed by a formal break in studies. After the break the research project was reconsidered in context of changes to practice and emerging literature. Data collection and analysis for the two subsequent pieces of research were completed in 2010 and 2011.

The aim of this collective research is to provide a broad overview of care provided for RhD negative pregnant and postnatal women in the UK, from a midwifery perspective. The objectives being: to describe current policy and practice, to understand what mistakes are made and why, and to seek a midwifery perspective on those aspects of care. The three pieces of research, their specific aims, methods and justification for undertaking them are described in subsequent chapters. The key theme of this research is development of an understanding of how and why midwives practise in relation to care of pregnant and parturient women with an RhD negative blood group.

The thesis consists of eight chapters. Chapter one provides an introduction to the research, Chapter two gives background to the physiology of RhD blood type and why it is significant during pregnancy, Chapter three is a review of the literature concerning the issues pertinent to the thesis. Chapter four outlines the aims and objectives of the studies and gives a broad overview of the approach used for each of the three different pieces of research that make up the thesis. This chapter also provides other significant information such as ethical considerations. Chapter five, six and seven present the three separate pieces of research providing background,

methods, data analysis, and findings specific to those particular pieces of work. In the final chapter, Chapter eight, the findings of the three strands of work are considered in relation to each other and discussed in the context of the thesis as a whole.

Chapter 2: RhD Negative Blood Type and Pregnancy

This chapter provides background information about care provided for pregnant and parturient women with a Rhesus D (RhD) negative blood group in the United Kingdom (UK). It describes the physiology of RhD negative blood types, the problems they can cause during pregnancy and the use of anti-D immunoglobulin to prevent this. The following chapter, Chapter three, outlines further relevant literature in more detail.

2.1 RhD blood type and maternal sensitisation

Human blood can be categorized by the ABO system; in addition it is also often described as either Rhesus positive or Rhesus negative. There are several Rhesus antigens, but D is the most prevalent and the description of blood type as Rhesus positive or negative commonly refers to the presence or absence of the Rhesus D (RhD) antigen (Turner, 2001). Around 16% of the UK population has RhD negative blood, although this varies between ethnic groups. For example only 5% of West Africans are RhD negative and the blood type is practically non-existent in Chinese people (Contreras, 1998).

People who are RhD negative may produce anti-D antibodies if RhD positive red blood cells enter their blood stream. This can happen either by transfusion of RhD positive blood or, more commonly, during a pregnancy with an RhD positive fetus.

Fetal and maternal circulations are distinct with fetal and maternal blood separated by the placenta. Occasionally fetal blood does pass into maternal circulation and this is known as feto-maternal haemorrhage (FMH). FMH may result in a maternal immune response and production of anti-D antibodies. Once formed the anti-D antibodies will always remain in the mother’s circulation and may become active should further contact with RhD positive blood occur, for example during a subsequent pregnancy with an RhD positive baby. This reaction is known as sensitisation, or immunisation, and is permanent and irreversible.

2.1.1 Haemolytic disease of the fetus and newborn

Sensitisation with anti-D antibodies is of little physical consequence to a person unless they require a blood transfusion, in which case they should receive antigen specific blood to avoid a haemolytic transfusion reaction. However, a potentially very serious consequence of maternal sensitisation is haemolytic disease of the fetus and newborn (HDFN). Many different anti-red cell antibodies can cause HDFN, including anti-c and anti-K (Kell), but the work described here relates to maternal sensitisation with RhD antibodies.

RhD HDFN is a condition in which a fetus or newborn infant's red blood cells are destroyed by maternal anti-D antibodies. This only happens when a sensitised RhD negative woman becomes pregnant with an RhD positive baby: the maternal anti-D antibodies are able to cross the placenta and can attack RhD positive fetal red blood cells, destroying them. HDFN is unlikely to cause problems for the pregnancy that causes sensitisation, but in subsequent pregnancies an RhD positive fetus will be at risk, an RhD negative fetus is not at risk. Destruction of fetal red blood cells can begin during intrauterine life and may lead to severe anaemia, hydrops fetalis and possibly death in-utero. In live born infants anaemia and jaundice caused by hyperbilirubinaemia worsens in the first few days of life. One of the most serious consequences of HDFN is kernicterus, damage to brain tissue due to high levels of bilirubin. Advances in antenatal and neonatal investigations and treatment mean that severe HDFN is now very rare.

2.2 Preventing maternal sensitisation: anti-D immunoglobulin prophylaxis

Anti-D immunoglobulin is a manufactured blood product that contains a high concentration of anti-D antibodies. It is prepared from plasma from sensitised donors. In the early 1960's it was recognised that intramuscular administration of anti-D immunoglobulin (Ig) could clear RhD positive fetal red blood cells from maternal circulation and prevent sensitisation from occurring (Contreras, 1998). This finding led to the recommendation in 1969 that anti-D Ig should be offered to all

RhD negative women after delivery of an RhD positive baby (postnatal prophylaxis). The early 1970s saw widespread introduction of anti-D Ig postnatal prophylaxis across the UK and a subsequent dramatic fall in deaths attributed to HDFN. In 1977 18.5 deaths per 100,000 live births were registered as due to haemolytic disease of the fetus or newborn; by 1989 this figure had fallen to just 1.5 per 100,000 live births (Hussey and Clarke, 1991). The policy was so successful that it was hailed as “a major obstetrical achievement” (Crowther and Middleton, 1999, Pg2).

The original policy was updated in 1976, 1981 and in 1991 extending the recommendation for prophylactic anti-D Ig to women with an RhD negative blood type who had an abortion and included several other events after which it was recognised that women may be more likely to develop antibodies. These events are known as potentially sensitising events and include delivery of an RhD positive baby, invasive procedures such as amniocentesis, antepartum haemorrhage and blunt abdominal trauma (Lee et al, 1997). To be effective a recommended standard dose of anti-D Ig (according to gestation) should be given within 72 hours of an event occurring. In addition a test, such as the Kleihauer test, should be used to estimate the size of any feto-maternal haemorrhage with additional anti-D Ig given if indicated.

Without anti-D Ig prophylaxis a pregnant RhD negative woman carrying an RhD positive baby has a 17% chance of immunisation with each pregnancy (Contreras, 1998). In the United Kingdom, with the widespread use of anti-D Ig prophylaxis, the current rate of sensitisation among RhD negative pregnant women is estimated at between 1.2% and 1.8% (NICE, 2008). Table 1 (below) summarises current UK policy for prevention of maternal sensitisation with anti-D antibodies.

Table 1: UK policy for use of anti-D Ig prophylaxis to prevent maternal sensitisation

	Less than 12 weeks gestation	12–19 weeks gestation	20 weeks or more gestation	Routine antenatal anti-D prophylaxis (RAADP)	Postnatal
When?	Within 72 hours of: Termination of pregnancy; uterine surgery; unusually severe pain or bleeding	Within 72 hours of: Any vaginal bleeding; blunt abdominal trauma; invasive antenatal testing; external cephalic version; stillbirth; intra-uterine death; miscarriage; termination of pregnancy; uterine surgery; ectopic pregnancy		Single Dose Regimen: 28 weeks Two Dose Regimen: 28 weeks and 34 weeks	Within 72 hours of: Delivery of RhD positive baby
How Much?* (recommended minimum dose of anti-D Ig)	250iu	250iu	500iu	Single dose regimen: 1500iu Two dose regimen: 500iu x 2	500iu
Kleihauer Test (or equivalent) **Required?**	Not Required	Not Required	Yes	Not Required	Yes Also require cord blood sample to test baby's blood type
*NB: If the Kleihauer test shows feto-maternal haemorrhage (FMH) larger than would be covered by standard dose of anti-D Ig (>4mls FMH), additional anti-D Ig and further Kleihauer testing will be required as instructed by the laboratory according to individual test results and clinical factors.					

Source: British Committee for Standards in Haematology, Guidelines for use of prophylactic anti-D immunoglobulin, 2006.

2.2.1 Routine antenatal anti-D Ig prophylaxis (RAADP)

The anti-D Ig programme resulted in a dramatic drop in deaths related to haemolytic disease in the UK (Hussey and Clarke, 1991), but, despite the decrease, there remain around 17 fetal and neonatal deaths per year attributed to RhD HDFN (NICE, 2002). Residual morbidity and mortality related to RhD HDFN is due to maternal sensitisation that occurs as a result of failure to administer anti-D Ig in line with guidance or due to silent sensitisation (Urbaniak, 1998, Van Dijk, 1997). Silent sensitisation is maternal sensitisation that occurs in the absence of any potentially sensitising event such as vaginal bleeding or abdominal trauma and it most often happens during the third trimester of pregnancy.

Routine antenatal anti-D prophylaxis (RAADP) is offering anti-D Ig to all RhD negative pregnant women during the third trimester of pregnancy, whether or not they experience a potentially sensitising event. It aims to prevent silent sensitisation by maintaining a prophylactic level of anti-D Ig in maternal circulation during the third trimester. In the UK, RAADP was first recommended in 1998 following a joint meeting of the Royal College of Physicians of Edinburgh and the Royal College of Obstetricians and Gynaecologists (RCOG). The outcome of the meeting was a consensus statement on prophylactic anti-D Ig recommending that all RhD negative pregnant women should be given anti-D Ig prophylactically (RCOG, 1998). In 2002 the National Institute for Clinical Excellence (NICE) conducted a Technology Appraisal (TA) on RAADP. This examined clinical and cost effectiveness and led to the recommendation that all RhD negative pregnant women in the UK should be offered RAADP (NICE, 2002). The Health Technology Board for Scotland (HTBS) and the Department of Health, Social Services and Public Safety (DHSSPS) in Northern Ireland both endorsed the recommendation.

Both the RCOG and the NICE guidance recommend that all pregnant women should be offered an injection of 500 IU anti-D Ig at 28 weeks gestation and again at 34 weeks gestation. An alternative product is also available providing a single dose of 1500 IU anti-D Ig given at 28 weeks gestation. There is some evidence that

compliance with guidance may be improved by using a single dose regimen (McKenzie et al, 2006 and 2011) and some authors have considered that the clinical implications of offering a single injection are beneficial in terms of resources and organisation (Chilcott et al, 2004). Both regimens have been shown to be effective, and the NICE TA review in 2008 revised the guidance stating that either regimen could be offered (NICE, 2008).

The NHS in England and Wales has a statutory obligation to provide funding and resource for all medicines and treatments that NICE recommends. However it is acknowledged that cost remains a significant factor in an NHS Trust's decision about whether to offer a specific treatment, and about which product to offer. The financial cost of offering RAADP is very substantial, with the gross cost of providing RAADP to all RhD negative pregnant women in England and Wales estimated at around £6.07million per year (Chilcott et al, 2004).

UK maternity units were slow to start offering RAADP, with Chilcott et al (2004) reporting that by 2001 only 12% of maternity units in England and Wales offered RAADP. In 2004, when this work commenced, there was little information about how many maternity units offered RAADP although the researcher knew through personal experience and communication that many still did not. The survey conducted as part of this research (Chapter five) found that in 2005 75% of UK maternity units offered RAADP (Harkness et al, 2008). In Scotland all maternity units now offer RAADP, but the current state of implementation in England and Wales is not clear. In 2008 the Public Ombudsman for Wales upheld a complaint from a pregnant woman whose local health board did not offer RAADP (Public Services Ombudsman for Wales, 2009).

2.3 Anti-D immunoglobulin: potential risks

There are clear benefits from administration of anti-D Ig however it is also associated with some risk. Anti-D Ig is manufactured from human plasma and as a human blood product it carries a risk of transmission of viral infection.

Transmission of hepatitis C via contaminated anti-D Ig is known to have occurred in Ireland between 1977 and 1979 (Lawlor and Columb, 1999), and during 1978 and 1979 a single source outbreak of hepatitis C occurred in 2533 German women who had received virus contaminated anti-D Ig (Meisel et al 1995). Dumasia (1989) also reported contamination of anti-D Ig with human immunodeficiency virus (HIV) in India in 1988 however there are no reports of any transmission to pregnant women.

The cases of hepatitis C contamination in Ireland and Germany occurred prior to the introduction of hepatitis C screening of blood donors. In the UK anti-D Ig is manufactured from pools of plasma from a large number of donations. All plasma donations are now tested for hepatitis B, hepatitis C and HIV. When the plasma is pooled all testing is repeated using validated methods, in addition all plasma pools are tested as part of a batch release procedure for blood products. To further reduce the risk of viral transmission anti-D Ig is subject to solvent/detergent treatment, a process known to be effective against enveloped viruses such as HIV, hepatitis B and hepatitis C, although of limited value against non-enveloped viruses such as hepatitis A and parvovirus B19 (Bio Products Laboratory (BPL), 2012). Since the widespread introduction of anti-D Ig prophylaxis in the early 1970's there have been no recorded incidents of viral transmission in the UK, or in North America where anti-D Ig is manufactured using a similar method (Urbaniak, 1998). Bio Products laboratory (BPL), one of the major manufacturers of anti-D Ig in the UK estimate that the risk of transmission of known viruses through anti-D Ig is around 1 in 10,000 million doses (BPL, 2012)

Anti-D Ig can only be screened for the presence of known viruses for which screening tests are available. The risk of transmission of new variant Creutzfeldt Jakob Disease (nvCJD) is impossible to quantify and there are currently no screening tests available. In May 1998 the Committee of Safety of Medicines recommended that all plasma products be manufactured from non-UK plasma. Plasma for the manufacture of anti-D Ig is now collected from donors within the European Union or the United States of America.

Improved screening tests and production technique mean that the risk of viral transmission in anti-D Ig is very small, nevertheless “a potential risk remains of known and unknown viruses for which screening tests are not available” (Urbaniak, 1998, Pg14).

Another potential risk associated with the use of anti-D Ig during pregnancy is the risk of transfer of anti-D Ig to the fetus, which would be expected to cause anaemia. Clinical trials show no such adverse effect and Urbaniak (1998) concludes that although anti-D Ig may cross the placenta the amount is insufficient to cause observable anaemia in the fetus or neonate. This is also reflected by the work of Maayan-Metzger et al (2001) whose research compared 101 study babies with 37 control babies. They found no difference in haemoglobin levels between the study babies, whose RhD negative mothers had received one or two doses of anti-D Ig, and the control group of babies born to RhD positive mothers who had not received anti-D Ig.

Another documented side effect of anti-D Ig is hypersensitivity however the effects, including rash and nausea, are almost always mild. Severe allergic reaction is extremely rare (BPL, 2012, Urbaniak, 1998).

2.4 Midwives’ role in anti-D Ig prophylaxis

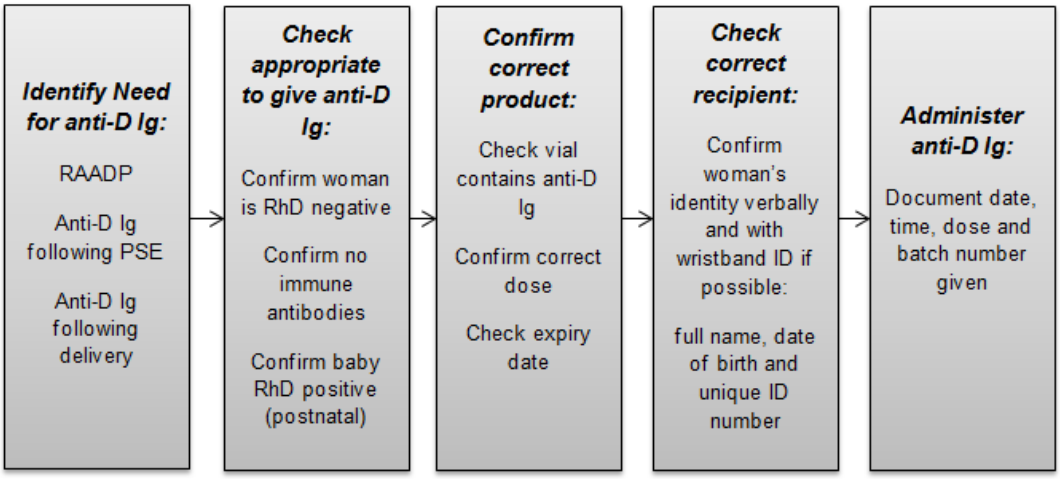
In the UK midwives are the key care providers for the majority of pregnancies. Regarded as experts in normal pregnancy they work closely with obstetricians and general practitioners to provide maternity care during pregnancy, around the time of birth and in the postnatal period. In an uncomplicated pregnancy a woman might receive all of her maternity care from a midwife without ever seeing a member of medical staff. Women with complications during pregnancy will most often receive multi-disciplinary care, led by a consultant obstetrician and with significant input from midwives.

RAADP and postnatal anti-D Ig prophylaxis are regarded as part of routine care and in most maternity units in the UK midwives will identify a need for anti-D Ig,

discuss this with the woman concerned, offer anti-D Ig and may prescribe and administer it if the woman agrees. Potentially sensitising events (PSE) during pregnancy such as vaginal bleeding, amniocentesis and blunt abdominal trauma are all regarded as complications and as such would require medical input. In these cases the midwife would often be the first point of contact for the woman and be the person who advises her whether or not to attend for assessment. An obstetrician will then make the decision about whether anti-D Ig is appropriate and complete a prescription. In most cases the midwife will then go on to administer the anti-D Ig.

The process that a midwife should follow prior to administration of anti-D Ig, including necessary checks, is detailed in Figure 1 below.

Figure 1: Procedure for administration of anti-D Ig



NB: The midwife must also engage the woman in a process of informed decision making. This process may span a number of occasions and might encompass provision of written information and discussion. This should result in the woman accepting or declining anti-D Ig prior to administration of the product.

2.4.1 A midwifery perspective on RAADP

Midwives are considered experts in normal childbirth with the philosophy of midwifery care underpinned by the ideal that pregnancy and childbirth are fundamentally normal processes. The midwifery paradigm acknowledges the

significance of women's individual differences and offers care that is based on the specific needs and choices of a particular woman. This approach recognises the importance of empowering women through involving them in decisions about their care, and that the subsequent impact on their self worth and confidence has far reaching consequences for them and their families (Leap, 2009). In contrast the biomedical approach views childbirth as an inherently risky process that may only be described as normal in retrospect. It relies on evidence based on a population perspective to decide what the 'best option' for women is. As a result the medical paradigm tends towards treatment as a pre-emptive measure, whereas the midwifery approach will wait until there is evidence that intervention is required (Rooks, 1999).

The Royal College of Obstetricians and Gynaecologists (RCOG, 1999) recommendation for a policy of offering anti-D Ig routinely during pregnancy (RAADP) was controversial. Midwives voiced strong concerns about the introduction of this routine intervention that would see all pregnant women with an RhD negative blood type offered a blood product (RCM, 1999). Although anti-D Ig is generally regarded as a very safe product, it is not without risk. Those risks are particularly difficult to quantify as they are based on unknown factors (Section 2.3, Pg 9) and, equally, the benefits of RAADP are difficult to ascertain at an individual level as the likelihood of benefit is impacted by factors that are most often unknown at that time. These include the blood type of the unborn baby, whether or not the woman will go on to have another pregnancy, and if she does what the blood type of any future baby or babies will be. The decision making process around RAADP is very important, but is also difficult for midwives to facilitate effectively: requiring knowledge and understanding of the issues; confidence in their ability to engage in discussion of this nature and additional time for that discussion. The recommendation to establish clinical policy to offer a blood product to all pregnant women with an RhD negative blood type makes it imperative that those women know and understand the risks and benefits of what they are being offered. It has been suggested that when intervention is routine policy midwives' primary allegiance becomes to their employer rather than to the woman and that they may

gather informed consent rather than offer informed choice (Thompson, 2013). Presenting RAADP as a choice for women within the scope of it being 'recommended' was recognised by the midwifery profession as vital but also as significantly challenging (RCM, 1999).

Concerns about the recommendation for RAADP can also be understood in the context of medical and midwifery approaches to care. The midwifery paradigm is one of woman centred care that takes into account individual differences and 'routine' intervention is inherently inappropriate. The evidence for recommending RAADP (RCOG, 1999, NICE, 2002) was based on a population gain, rather than on any potential benefit for a particular woman. As such a policy of offering RAADP represents 'routine' pre-emptive intervention without evidence of benefit for a particular individual, fundamentally conflicting with the midwifery approach to care. Walsh and Newburn (2002) express concern that the routinisation of clinical practices is an example of how maternity services centre around the professional rather than the woman, and the concerns that were raised by midwives focused on potential for failure to provide woman centred care if anti-D Ig was offered to all RhD negative women in a routine manner (RCM, 1999).

As a midwife working for the Scottish National Blood Transfusion Service (SNBTS), the researcher was vitally aware of the contrast between the medical, scientific and midwifery approaches to care for pregnant women with an RhD negative blood type. The researcher's experience was that policy and evidence in this area reflected a biomedical approach to information gathering that appeared to separate the woman's physiology from her experiences and her social and emotional context. In general the scientists and haematologists who establish policy, and ultimately practice, in this field appeared to consider that the only evidence of value was that which demonstrated physiological impact through what they regarded as scientifically robust quantitative experimental research. This contrasted with the midwifery approach that would consider the woman as important at an individual level and encompass a number of aspects other than physiology that might impact

outcomes, with the option of gathering evidence from sources other than experimental research.

The RCOG (1999) and subsequent NICE (2002) recommendation for a policy of RAADP in the UK required midwives to assume responsibility for offering and subsequently administering anti-D Ig to all pregnant women with an RhD negative blood type. This greatly increased their involvement in this area of practice, yet as a profession they made very limited contribution to policy and published evidence in this field. It is of note that midwives were not included in the 1998 consensus conference that led to the recommendation for RAADP (RCOG, 1999). Their subsequent concern, after the event (RCM, 1999), reflects the observation of Walsh and Newburn (2002, Pg476) that midwives often find themselves 'reacting to, not proactively engaging with, the latest initiatives.'

The following chapter, Chapter three, considers available evidence about the care of RhD negative pregnant and postpartum women in greater depth. The contrast between medical and midwifery approaches, the midwifery perspective on anti-D Ig policy and the concerns raised about a policy for routine antenatal anti-D Ig are discussed in greater detail in Section 3.5.1, Pg 51.

Chapter 3: Professional and Organisational Issues: a review of the literature

The overall aim of this research was to describe practice and policy surrounding the care of women with an RhD negative blood type from a midwifery perspective. The objectives being to describe midwifery practice in relation to women with an RhD negative blood type and to develop an understanding of the contribution that midwives make to this aspect of maternity care.

Within this overall aim there were three distinct aims:

- To determine current UK policy in relation to the NICE (2002) recommendation for routine antenatal anti-D Ig (RAADP). With the objective of describing aspects of policy, and its implementation, that impact clinical midwifery practice.
- To describe anti-D Ig errors made by midwives. With the objective of gaining a wider understanding of the types of mistakes made and the factors that influence them.
- To explore midwives' perspectives on the care provided for women with an RhD negative blood type. With the objective of eliciting their views concerning questions identified from the previous research and in existing evidence.

The literature review was initially focussed on practice and policy concerning women with an RhD negative blood type exploring: development of policy; the physiological and scientific basis for policy and guidance; and studies relating to actual clinical practice. As the literature review progressed the search was widened in order to address the further aims and objectives of the research and the emerging themes within the evidence.

One topic that became central to the literature review was quality. The Oxford English Dictionary (2014) defines quality as 'the degree of excellence of something', and within the NHS quality is central to existing policy.

The medical and midwifery perspectives (discussed in Sections 2.4.1 and 3.5.1) have different approaches to defining and measuring quality. The biomedical approach tends towards defining quality in healthcare as based solely on clinical outcomes, employing checks and balances to determine and maintain their ideal of quality. The midwifery approach, however, would encompass the 'whole' experience, including the woman's perception of whether her care was good or bad. Within this work it was deemed important to explore quality from a midwifery perspective, including not only objective clinical outcomes but also those other factors that might determine quality care within a midwifery paradigm.

When the care of women with an RhD negative blood type is considered within a biomedical framework of quality it focuses on delivering safe and effective clinical care, principally in order to prevent maternal sensitisation with anti-D antibodies. This is measured through checks based on adherence to clinical recommendations and guidelines, and audited by incident reporting and clinical outcomes. The midwifery approach, however, considers that provision of woman centred care, including making an informed decision about whether anti-D Ig is right for a particular woman, is equally important to quality. This wider view of quality care in relation to women with an RhD negative blood type was deemed fundamental to the framework on which this research was based and as such 'quality' features as central to the literature presented here.

An important aspect of quality is provision of safe and effective care. The literature review includes examination of factors that impact on this including incident reporting and investigation. The research presented in Chapter six: Anti-D Ig, analysis of midwifery errors reported to SHOT has as its aim 'to describe anti-D Ig errors made by midwives'. As there is little information directly relating to anti-D Ig in this area, much of the evidence considered here relates instead to medication errors.

Another fundamental aspect of quality care for RhD negative women and a key feature of midwifery practice is informed decision making. This was another subject area that was explored within the literature review.

The aim of the third piece of research, Chapter 7: Focus group research to gain a midwifery perspective, was to explore midwives' perspectives on the care provided to RhD negative women. This, and the overarching aim of determining a midwifery perspective on care, required exploration of what a midwifery perspective is and how this may differ from a medical or scientific approach. This was done through review of literature pertaining to the 'midwifery model' and around medicalisation of childbirth.

The literature review is wide ranging and aims to address the issues pertinent to the overarching, and the more specific, aims and objectives of the research.

3.1 Search Strategy

The literature review was undertaken using the Knowledge Network resource (www.knowledge.scot.nhs.uk) to search the following databases: Ovid, including Medline and MIDIRS; CINHAL and the Cochrane Library. The overarching search terms were: anti-D immunoglobulin; Rhesus; Routine antenatal anti-D and Haemolytic disease of the newborn. Various synonyms and abbreviations such as: RhD; Rhesus D; Rhesus negative; RAADP; Rhesus disease; anti-D Ig and HDN were also used, as were combinations of terms. The search was limited to English language and there was no date limit. Similarly the country of origin of articles was not limited, however articles were considered individually for relevance to the aims of this research in the context of practice within the UK. This resulted in some international, English language, articles being excluded. Articles deemed no longer relevant due to age were also excluded using the same process. The inclusion criteria for the literature were studies, articles and evidence that focussed on, or were relevant to, the physiology, treatment and/or clinical care of pregnant and parturient women with an RhD negative blood type in the UK.

As the research progressed further searches were made such as quality in health care, including: clinical governance; adverse events; incident reporting and informed decision making, and midwifery, including: midwifery model; medicalisation of childbirth; midwifery profession.

Reference lists within identified articles were scrutinised in order to identify any further relevant literature not uncovered by the initial search. In addition books, articles, abstracts and policy documents recommended by colleagues, advisors and supervisors and encountered through work with the Scottish National Blood transfusion Service (SNBTS) were also considered for inclusion.

The literature was first searched in 2004, and the search was repeated regularly throughout the work to ensure that any new evidence would be considered.

A significant number of the articles referred to in the literature review were published during the 20th century. The consensus statement that first recommended routine antenatal anti-D (RAADP) in the UK resulted from a joint meeting of the Royal College of Physicians of Edinburgh and the Royal College of Obstetricians and Gynaecologists (RCOG). This was held in 1998 at a time when there was heightened interest in care provided for pregnant women with an RhD negative blood type. Although it almost exclusively pre-dates 1998, it was important and relevant to discuss the evidence considered at the joint meeting as that evidence led to the recommendation for RAADP (RCOG, 1999, NICE, 2002). The heightened awareness surrounding the joint meeting and consensus statement (RCOG, 1999) resulted in a number of articles concerning RAADP, anti-D Ig and care provided for women with an RhD negative blood type. These were also published around this time, and were also important and relevant to the thesis.

3.2 Quality in the NHS

In 1997 the newly elected Labour government introduced a 10 year programme with the aim of renewing and improving the NHS: ‘The New NHS Modern-Dependable’ (DOH, 1997). Quality was regarded as being at the heart of this approach with the

subsequent white paper ‘A first Class Service: Quality in the New NHS’ (DOH, 1998) outlining wide ranging quality focused ambitions for the ‘new NHS’.

The term ‘quality’ is difficult to define. In 2008, Lord Darzi published a next stage review ‘High quality care for all’, a huge consultation involving over 60,000 staff, clinicians, patients and members of the public. The report offered a definition of quality as “[care which is] clinically effective, personal and safe” (Darzi, 2008, Pg8/9), and this definition is now widely used. In addition there are six internationally recognised dimensions of a quality framework: person-centred; safe; efficient; effective; equitable and timely (Scottish Government, 2010a).

In Scotland healthcare policy has broadly mirrored that in the rest of the UK, and the publication in 2010 of ‘The Healthcare Quality Strategy for NHS Scotland’ reinforces the importance of quality within healthcare policy in Scotland, and echoes Lord Darzi’s assertion that the NHS should have quality at its heart. The report describes three quality ambitions that provide the focus for prioritising and integrating activity across Scotland, these are: safe, effective and person-centred.

The report ‘An Organisation with Memory’ (Department of Health, 2000) acknowledged that although the majority of care given within the NHS is of a very high standard, serious failures do occur. This has important implications for individual patients and staff members, and potentially undermines public confidence in the organisation. It also carries a large financial burden. Patient safety is seen as key to delivering quality in the NHS, and for most countries, worldwide, patient safety is the most significant issue in healthcare quality and risk management (National Audit Office, 2005). The National Audit Office offers a definition of a patient safety incident as:

> “Any unintended or unexpected event that lead to death, disability, injury, disease or suffering for one or more patients”
>
> (National Audit Office, 2005, Pg1)

Estimates suggest that in the UK adverse events that harm patients occur in around 10% of hospital admissions, a rate similar to other high resourced countries, costing the NHS an estimated £2billion a year (National Audit Office, 2005 and Department of Health, 2000). In the United States, population based research suggests that between 44,000 and 98,000 patients die each year from preventable errors, making medical error the eighth most common cause of death (Sexton, Thomas and Helmreich, 2000). The National Audit Office states that the most common reported adverse incident are patient injury due to falls, followed by medication error, although others report that medication errors are the largest source of error in the health care system. Nemeth and Wessell (2010) found a frequency of prescribing error of between 0.3 per cent and 39 per cent, depending on the definition and the method employed in their detection. They estimate that around fifty per cent of the medication errors were preventable. Their research found that although significant opportunities exist to identify preventable medication errors and intervene before potential harm, effective interventions to prevent them are limited. This echoes National Audit Office estimates that around fifty per cent of adverse incidents could have been avoided if lessons from previous incidents had been learned (Department of Health, 2000).

The report ‘An Organisation with Memory’ (Department of Health, 2000) placed great emphasis on patient safety and led to the establishment of the National Patient Safety Agency (NPSA) in 2003. The aim of the NPSA is to improve safety and quality of care though reporting, analysing and learning from patient safety incidents and near misses. In Scotland Quality Improvement Scotland (QIS) oversaw quality and risk management issues before the launch of the Scottish Patient Safety Programme (SPSP) in 2008. Hailed as the first national patient safety programme in the world it aims to reduce adverse events in hospitals by 30% and mortality rates by 15%, by 2012 (NHS Scotland’ Chief Executive’s Annual Report 2009/10). The SPSP is part of the NHS Scotland organisation Healthcare Improvement Scotland (HIS) which describes one of its key priorities as supporting clinical governance: a system

of checks and balances that ensures clinical services are of the highest possible quality (SPSP, 2011).

In 1998 it became a statutory duty of all health organisations to seek quality improvement through clinical governance, a framework by which policy makers have attempted to improve quality within the NHS. Scally and Donaldson define clinical governance as:

> "a system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish"
>
> Scally and Donaldson (1998, Pg 62)

Accountability, of both individuals and of organisations, is integral to the delivery of quality care, with clinical governance in turn regarded as integral to the planned modernisation of the NHS (DOH, 1997). Clinical governance applies NHS wide and seeks to address variations in standards of care within the organisation. The framework of clinical governance is described as having seven pillars: Clinical effectiveness; risk management; patient experience and involvement; communication; resource effectiveness; strategic effectiveness; learning effectiveness.

Risk management was initially focused on reducing litigation and compensation payments. Recognition of the need to reduce harm developed over time and now the term risk management includes strategies to reduce harm and improve the quality of care (Vincent, 1995). At the heart of most systems of clinical risk management are methods for early identification of adverse events, using either staff reports or systematic screening of records. Identification of adverse events allows recognition of common patterns and prevention of future incidents.

3.3 Quality of care: pregnant and postpartum women with an RhD negative blood type

Quality of care for pregnant women with and RhD negative blood type is important in order to prevent unnecessary sensitisation with anti-D antibodies and subsequent Haemolytic Disease of the Fetus and Newborn (HDFN). Application of clinical guidance to ensure women are offered appropriate anti-D Ig prophylaxis is one aspect of this, however enabling women to recognise when to seek help and make decisions about the most appropriate care for them is also an important aspect of quality of care for this group.

When the Royal College of Obstetricians and Gynaecologists (RCOG) recommended that all pregnant women with an RhD negative blood type be offered RAADP, some midwives argued that such mass intervention should be delayed until failures in current care for those women were addressed (RCM, 1999). The midwives contended that a significant reduction in rates of sensitisation might be better achieved through improving practice in relation to existing {1991} guidance for the use of anti-D Ig (RCM, 1999).

There is a great deal of evidence that some aspects of care provided for pregnant women with an RhD negative blood type, in relation to prevention of maternal sensitisation, is poor. Non-compliance with guidelines for anti-D Ig administration has been suggested as a significant contributing factor for continuing maternal sensitisation by a large number of authors including Vause, Wray and Bailie (2000) Howard et al (1997) Van Dijk (1997), Letsky and De Silva (1994), Ghosh and Murphy (1994).

3.3.1 Anti-D Ig prophylaxis: potentially sensitising events and postnatal prophylaxis

Several studies have explored compliance with the 1991 recommendations for the administration of anti-D immunoglobulin (Vause, Wray and Bailie, 2000, McSweeney et al, 1998, Howard et al, 1997, Morrison, 1997, Ghosh and Murphy, 1994.) All of these studies were retrospective audit of case notes and all have similar

findings. The findings suggest that on the whole, postnatal management of RhD negative pregnant women is effective and complies with current guidelines. However, all of the studies also describe poor adherence to guidelines and sub-optimal management of antenatal potentially sensitising events.

Retrospective audit of case notes presents several difficulties in examining information, in terms of both accessing actual case notes and in the accuracy of record keeping and documentation within the case notes. Maternity services are particularly susceptible to this problem. Often care is shared between hospital and community staff, such as General Practitioners and Community Midwives, with staff documenting antenatal care in separate notes. Hand held patient records might lead to further duplication, or misplacing, of documentation. The validity of studies that rely on retrospective audit of case notes is dependent on accurate documentation of maternal blood testing, administration of anti-D Ig and reporting and documentation of potentially sensitising events, actions over which the authors have no control.

A study that illustrates the limitations of this research methodology is that of McSweeney et al (1998). McSweeney et al (1998) completed a retrospective study of all new cases of RhD sensitisation occurring in Yorkshire between 1988 and 1991. Data was analysed for 129 women with 312 pregnancies. Ninety eight potentially sensitising events were identified, only 58 (59%) were included in the analysis as full information was not available in the other cases. Information was not available for events that had taken place out with the NHS, such as termination of pregnancy in private clinics, or for events occurring prior to hospital booking at around 12 weeks gestation.

McSweeney et al (1998) report that 79 (81%) of the 98 sensitising events identified were miscarriage and termination of pregnancy. As previous pregnancies are routinely and clearly documented in maternity notes, miscarriage and termination of pregnancy are events that are least likely to be omitted from notes. This study highlights the problem of undocumented potentially sensitising events that will not be picked up during retrospective case note analysis. Reporting and documentation

of a potentially sensitising event is dependent on the woman recognising and reporting an incident when it happens. If she is unaware of the significance of an event, it may go unreported and therefore undocumented. If a pregnant woman does report a sensitising event there is no guarantee that it will be documented. In particular if a woman seeks informal advice by telephone from a midwife or general practitioner after an event such as a small bleed or abdominal trauma (such as a light fall or knock to her abdomen), this may not be documented at the time. If the practitioner recommends no further action, or if the woman chooses to ignore advice to attend formally, there may be no record of the event in her notes.

Interestingly McSweeney et al (1998) found that only 5.4% of women experienced antepartum haemorrhage and 0.7% antenatal abdominal trauma. In contrast the research of Howard et al (1997) found that around 32% of pregnant women experienced some form of bleeding during pregnancy and that 5% sought advice for abdominal pain or trauma. Wide variation of reported incidence of potentially sensitising events suggests inconsistency in documentation of events, rather than variations in incidence.

McSweeney et al (1998) found that guidelines for the management of RhD negative pregnant women were followed in only 17 (22%) out of the 98 identified antenatal events. The most common failures were omission of anti-D Ig, incorrect dose of anti-D Ig given and failure to perform a Kleihauer test. The authors conclude that educational programmes for midwives and nursing staff could be used to achieve better compliance with guidelines for care. Without acknowledging any limitations of their research, they also go on to state that a significant number of the cases of immunisation could be prevented with prophylactic antenatal administration of anti-D Ig, and illustrate this point by stating that 67 (52%) of the women who became sensitised had no identifiable sensitising event.

Three larger studies have examined compliance with guidelines for the administration of anti-D Ig in the United Kingdom (Vause, Wray and Bailie, 2000, Howard et al, 1997, and Ghosh and Murphy, 1994). The largest of the three, Vause,

Wray and Bailie (2000), involved a retrospective study of all RhD negative women who booked for care in NHS maternity units in Northern Ireland in 1996. Data were obtained on 3380 women, 106 were excluded from final analysis due to missing case notes or incomplete data. Data were available for analysis on 3274 women.

The audit was commissioned by the Department of Health in Northern Ireland and the Royal College of Obstetricians and Gynaecologists (RCOG) clinical audit unit co-ordinated the data collection and analysis. The researchers based their data collection on four 'auditable standards' developed from existing guidelines.

The four auditable standards were that:

1. All women should have their RhD group determined within four weeks of their first antenatal contact with a health care professional.
2. All women who are RhD negative should have antibody titre checked at least once after 28 weeks' gestation, and prior to their admission for delivery.

With the exception of women who have already developed anti-D antibodies all women who are RhD negative:

3. Must be offered an appropriate dose of anti-D Ig following a potentially sensitising event (PSE) in pregnancy (250 IU if less than 20weeks gestation, 500 IU and a test to assess the size of feto-maternal bleed if 20 weeks gestation and over).
4. Should be offered an appropriate dose of anti-D Ig, based on the result of a Kleihauer (or equivalent) test if their baby is found to be Rhesus positive.

Vause, Wray & Bailie (2000)

The data collection method was validated by a large multi-centred pilot study (Vause and Maresh, 1999) and was later refined for use. The study findings are illustrated in Table 2 (below), and show generally poor compliance with guidelines during pregnancy.

Table 2: Compliance with guidelines, summary of findings of Vause, Wray and Bailie (2000)

	PSE <20 weeks (n=264)	**PSE > 20 weeks** (n=319)	**Postnatal following delivery of RhD positive baby** (n= 1852)
Anti-D Ig given within 72 hours	117 (44%)	184 (58%)	1820 (98%)
Kleihauer test performed	N/A	25 (8%)	1748 (94%)
Managed in complete accordance with guidelines	N/A	19 (6%)	1656 (89%)

Vause, Wray and Bailie (2000) found that some types of potentially sensitising events were more likely to be managed appropriately than others. In particular of the 52 women reporting trauma during pregnancy, only 5 (8%) received anti-D Ig.

A major limitation of this study is that it was retrospective. As already mentioned, analysis of case notes presents difficulties in accessing information, both in terms of accessing actual cases notes and in inaccuracy of record keeping and documentation. The fact that this study was multi-centred will have compounded these problems.

Wray (2000) acknowledges these problems and outlines the methods used minimise problems related to data collection taking place in several centres and being conducted by several different researchers. The study adopted an action-orientated approach to facilitate local ownership and commitment. Interactive workshops and training sessions were held and all participants were in regular contact with the researchers and were supported locally by clinicians and managers. These measures will have helped minimise individual researcher bias in interpreting the medical notes. The problem of inaccurate documentation is a more pressing one and attempts

were made to overcome this through comparing the information in medical notes with the information held by the local blood transfusion service. This will have highlighted discrepancies in relation to laboratory tests and anti-D Ig administration, and although it does not counter the problem of inaccurate documentation of potentially sensitising events, the purpose of the research is to measure compliance with guidance rather than identification of all potentially sensitising events.

This research offers a large-scale study conducted by experienced researchers using sound research techniques. The limitations of using a retrospective case note analysis remain, however, and although the study highlights non-compliance with potentially sensitising events identified by the authors, the method does not allow for discrepancies in reporting of events or for lack of documentation. This is a problem for all three of the major studies in this field and the findings of Vause, Wray and Bailie (2000) are largely comparable with the research of Howard et al (1997) and Ghosh and Murphy (1994).

Howard et al (1997) examined case notes of 922 RhD negative women who delivered in seven maternity units in Merseyside during 1994. They identified 396 potentially sensitising events for which women should have received anti-D Ig, with anti-D Ig given within 72 hours in 235 of the 396 (59%) events and in a further five cases it was given later than this. The dose of anti-D Ig administered was recorded in 166 (69%) of the 240 cases where anti-D Ig was administered.

Howard et al (1997) also found that the Kleihauer test was used diagnostically for 22 women who presented with abdominal pain, with 14 women whose test result was negative not receiving any anti-D Ig. The authors also report that for 10 women who reported vaginal bleeding after 20 weeks gestation and four with abdominal trauma a negative Kleihauer test resulted in anti-D Ig being omitted. They do not state the total number of women who presented with potentially sensitising events after 20 weeks gestation.

Five hundred and twenty of the 922 study women gave birth to RhD positive babies, and anti-D Ig was given within 72 hours of delivery to 497 of them (95%). Anti-D Ig was administered to a further 226 mothers who delivered in hospitals where policy was that all RhD negative women should receive postnatal anti-D Ig, irrespective of their baby's blood type. It was also given unnecessarily to 55 women who were already known to be sensitised. Of the 14 women in whom the Kleihauer test indicated further anti-D Ig was required, only 9 received this.

A major limitation of this research is that Howard et al (1997) did not compare findings from medical notes with laboratory requesting and test results. There is also no information on whether hospital notes alone were examined, or whether General Practitioner notes were also accessed, which may have led to omission of details of potentially sensitising events reported during pregnancy. This work also highlights the differences in policies between hospitals in the UK, with some opting to administer postnatal anti-D Ig to all RhD negative women regardless of their baby's blood type. The authors also have an outcome of 'Kleihauer test taken after 12 weeks gestation' rather than National policy of over 20 weeks gestation. It is not clear if this reflected policy in the hospitals included in the study.

Ghosh and Murphy (1994) conducted the third major UK study concerning compliance with guidelines on the administration of anti-D Ig. In a retrospective case note analysis of 1120 pregnancies of RhD negative women in two Scottish regions, 671 of the 1120 women delivered RhD positive babies and 663 (99%) of these received anti-D Ig within 72 hours. Two hundred and eighty potentially sensitising events during pregnancy were identified and anti-D Ig was given in 195 (70%). The authors also looked at the cases where women had reported a vaginal bleed after 20 weeks gestation, and found that in only 9 out of 98 (9%) cases was a Kleihauer test performed. Detailed information on the methodology of this research was not available. However the authors do stipulate that data were collected from hospital, general practitioner and laboratory records by a single member of the study team.

In summary, the findings of studies looking at compliance with guidance for anti-D Ig prophylaxis are relatively consistent. Compliance appears to be good following delivery of an RhD positive baby, with anti-D Ig being omitted for only a small number of women. Potentially sensitising events during pregnancy were less well managed which may reflect the less routine nature of this type of event, coupled with the added complication of differing management depending upon the gestation of pregnancy. All of the studies demonstrated some confusion surrounding the use of the Kleihauer test and there would appear to be poor understanding of its purpose, when it should be used and how to interpret and act upon its result.

The studies described above all share the limitation of being retrospective analysis of cases notes. Poor documentation, might lead to some potentially sensitising events being under reported, but equally failure to document administration of anti-D Ig or Kleihauer testing could also contribute to over estimation of the same failures in care.

3.3.2 RAADP

Although there is a great deal of information about compliance with the earlier guidance, there remains little information about compliance with RAADP in the UK. When considering practice in relation to RAADP, it is important to examine not only whether a woman received the injection, but also the gestation at which it was given. The aim of RAADP is to maintain a prophylactic level of anti-D Ig in maternal circulation throughout the third trimester of pregnancy until delivery. Given too late, it will not protect at the start of the third trimester and given too early it will not maintain a prophylactic level until delivery, particularly if the pregnancy continues beyond 42 weeks gestation.

One study that has looked at this is McKenzie et al (2006) who considered compliance with RAADP at the John Radcliffe Hospital, Oxford, between 1992 and 2003 by conducting case note review. RAADP had been offered at the hospital since 1986 and the authors compared the case records of 365 women who delivered between 1992 and 1996, with 215 case records of women delivering between 1997

and 2003. In this case RAADP was offered as a two-dose regimen, with injections at 28 and 34weeks. The findings are summarized in Table 3 below.

Table 3: Compliance with RAADP, summary of findings of McKenzie et al (2006)

	28 week anti-D Ig received	28 week anti-D Ig received on time	34 week anti-D Ig received	Both injections received
1992-1996	309/347 (89%)	183/347 (53%)	273/337 (81%)	251/337 (74%)
1997-2003	171/191 (90%)	145/191 (85%)	165/190 (87%)	150/190 (79%)

The authors state that although there was no significant increase in the proportion of women receiving RAADP over time, the timing of the injections did improve. They concede however that documentation had improved over the years and that the findings may reflect improvements in documenting administration of anti-D Ig rather than actual administration. McKenzie et al (2006) also note that 3/350 (0.8%) of women refused RAADP in the period of 1992-1996, rising to 7/197 (3.5%) by 1997-2003.They reflect that this may have been due to heightened awareness of potential for infection due to blood products during the study period.

Another study that considered compliance with RAADP is that of Chaffe et al (2007). This study used a retrospective audit of the medical notes of 207 RhD negative women at two maternity units in England during 2004. The maternity units had both offered a two dose regimen, with anti-D Ig offered at 28 and 34 weeks. The main findings were:

- 150/207 (72%) of women had documented evidence in their notes that they had received written or verbal information about RAADP.
- 185/207 (89%) of women had informed consent documented in their notes

- 22/207 (11%) declined RAADP before the first dose
- 28/207 (13%) declined a second dose of RAADP after having a first
- Of the women who consented to receive RAADP, 98% received anti-D Ig within 1 week of 28 and 34 weeks.

This study has the limitations associated with retrospective case note analysis that have already been discussed in detail. That said, it is the only study to take into account maternal informed choice in relation to rates of compliance. This is important when looking at potential failures in provision of clinical care associated with RAADP, rather than overall impact on rate of sensitisation rate. This study found high compliance: 98% of women who wished RAADP receiving it in compliance with guidelines.

These two studies suggest that compliance with RAADP is good. This reflects evidence surrounding anti-D Ig administration following potentially sensitising events and postnatally, where compliance is generally good when care is routine and has become embedded in clinical practice.

3.3.3 Why do failures of care happen?

Importantly none of this literature tells us anything about why the failures in care occurred or how they might be prevented. The published evidence gives little consideration to how failures could be addressed or about what the potential impact of improved compliance might be on the rate of maternal sensitisation and subsequent HDFN.

One issue that has been discussed in relation to compliance with guidance for administration of prophylactic anti-D Ig is the knowledge and understanding of the health care professionals, midwives and medical staff, involved. Several authors have suggested that the poor rate of compliance with current guidelines is linked to poor understanding of the issues involved by those who provide care (Vause, Wray and Bailie, 2000, Howard et al, 1997, Van Dijk, 1997, Ghosh and Murphy, 1994). There has been no published evaluation of health professionals' knowledge in relation to

management of RhD negative women, however Wray (2000), Wickham (1999a), Saha (1998) and Van Dijk (1997) all suggest that the knowledge of midwives and other clinicians may be lacking.

It is unclear why there should be such a gap in the knowledge base in relation to the management of RhD negative women and it could be that failure to follow guidelines appropriately may reflect a more general problem of incorporating evidence into practice. Wray (2000) suggests that the debate over anti-D Ig administration raises a number of questions about the development of evidence in maternity care and its translation into practice.

In the UK there is no single approach to providing education about anti-D Ig for midwives. The subject should be covered by curriculum at undergraduate level, but it is not clear how qualified midwives then receive updates and on-going education on this aspect of clinical care or how changes to policy are implemented and supported.

Available evidence suggests that areas of practice where there is a standard response to a planned or routine event achieve the highest level of compliance with the guidelines. In the postnatal period, for example, almost all women (95-100%) receive care in line with guidelines (Vause, Wray and Bailie, 2000, McSweeney et al, 1998, Howard et al, 1997, Ghosh and Murphy, 1994). Around time of delivery effective management of RhD negative women appears to have been successfully integrated into practice. The only events during pregnancy to achieve similar rates of compliance are procedures such as amniocentesis and external cephalic version, after which 92-100% of women receive appropriate management (Howard et al 1997, Ghosh and Murphy, 1994). These events are planned and the need for anti-D Ig is not reliant on any further testing and it would appear that administration of anti-D Ig at this time has become established practice.

When a potentially sensitising event occurs spontaneously during pregnancy women are less likely to be offered management in accordance with guidance. Available evidence suggests that events such as falls, abdominal trauma and abdominal pain are unlikely to be correctly managed. Howard et al (1997) found that only five of 24

(21%) of women who had a fall or abdominal trauma and eight of 22 (36%) of those with abdominal pain were managed appropriately. Vause, Wray and Bailie (2000) also report that abdominal trauma during pregnancy was often not managed as a potentially sensitising event.

When managing potentially sensitising events during pregnancy appropriate use of a test for size of feto-maternal haemorrhage (FMH) and subsequent administration of a correct dose of anti-D immunoglobulin is another area where compliance with guidelines is extremely poor (Vause, Wray and Bailie, 2000, Howard et al, 1997, Ghosh and Murphy, 1994,). The test most commonly used in the UK is the Kleihauer test, a maternal serum test that will detect fetal red blood cells in excess of 4ml. This indicates a large FMH that requires a larger dose of anti-D Ig than is standard. The Kleihauer test, or equivalent, should not be used to determine whether or not anti-D Ig should be offered, it is intended only to ensure that an appropriate additional dose is given if required. Guidelines state that a test for FMH should be used after any potentially sensitising event occurring after 20 weeks gestation. There would appear to be general misunderstanding about the use of the Kleihauer test. Howard et al (1997) found that only 45% of the women in their study had a Kleihauer test performed after a potentially sensitising event at 20 weeks gestation or more. Vause Wray and Bailie (2000) also found that testing to assess the size of FMH was often omitted, making it impossible to ascertain whether an appropriate dose of anti-D Ig had been given. Both Howard et al (1997) and Ghosh and Murphy (1994) reported that a Kleihauer test was used diagnostically for 20-30% of women: that is clinicians believed that a negative result indicated that anti-D Ig not required, leading to a number of women who had reported a potentially sensitising event not receiving any anti-D Ig.

It would appear that when management of an RhD negative woman is routine practice clinician's adherence to guidelines is good, however when a potentially sensitising event occurs spontaneously during pregnancy, or if a Kleihauer test is indicated, there would appear to be some confusion among health care professionals about how to manage care most appropriately. This is of particular concern as a

Kleihauer testing is associated with increased risk of larger FMH, and so increased risk of sensitisation. Those cases where care is most likely to fail might also be the cases most likely to lead to sensitisation.

Another area where there would appear to be some question over practice, is the site in which the injection is given. Both the 1991 and the 1998 guidelines state that an anti-D Ig injection should be given in the deltoid muscle. Injection into the gluteal area may result in sub-cutaneous rather than intra-muscular injection, reducing effective absorption of the anti-D Ig (RCOG, 1999, Urbaniak, 1998). There is some anecdotal evidence that midwives favour the gluteal site and rarely inject into the deltoid muscle (Benbow and Wray, 1999).

3.3.4 Medication errors

There is little literature available to aid understanding of the factors that impact errors involving anti-D Ig, however there is a body of information about medication errors. There are a number of similarities between the process and circumstances of administration of medication in general and that of offering and administering anti-D Ig, and so it is useful to consider the evidence concerning medication errors in this context.

Medication errors are recognised as a significant cause of preventable harm to patients both in the UK (National Audit Office, 2005) and the United States (Sexton, Thomas and Helmreich, 2000). Anderson and Webster (2001, Pg35) cite Foley (1999) in stating that ‘it is estimated that adverse drug events are surpassed only by heart disease, cancer and strokes as a cause of death in the USA’. Several authors have also suggested that drug administration is one of the highest risk areas of nursing practice (Schelbred and Nord, 2007, Anderson and Webster, 2001, Gladstone 1995). However, the actual incidence of medication error is not well understood, with reported incidence varying significantly (from 0.3% to 39%) due to different methods of collecting data and of the differing definitions of error that are used (Nemeth and Wessell, 2010, Williams, 2007, Birch and Culshaw 2003).

Brady, Malone and Flemming (2009, Pg 680) define a medication error as:

'*any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer'*

It has been suggested that there is significant under-reporting of medication errors, with estimates varying from a rate of 50% to just 2% of errors being reported, depending on the professions involved (Duncan, 2004, Milch et al, 2006). During a review of literature concerning medication errors Brady, Malone and Flemming (2009) found a number of factors that impacted reporting of incidents. These factors included fear of disciplinary action, not being able to report anonymously, constraints on time and thinking it was unnecessary to report errors when there was no negative outcome. Other authors have also reported that lack of anonymity when reporting errors and a tendency towards a punitive 'blame culture' may lead to significant under-reporting of errors (Schelbred and Nord, 2007, Williams, 2007, Anderson and Webster, 2001, Gladstone, 1995). With several authors suggesting that omission of medication is the category of error that is most likely to be unreported (Williams, 2007, Birch and Culshaw, 2003, and Anderson and Webster, 2001).

Failure to report incidents not only means that it can be difficult to understand the true incidence of error, it also means that clinicians and managers are unable to fully investigate the cause of errors, limiting ability to learn from incidents and subsequent ability to put in place measures that might reduce likelihood of recurrence.

The work by Brady, Malone and Flemming (2009) was a systematic review of literature concerning individual and system factors that contribute to medication errors in nursing practice. They selected twenty six qualitative and quantitative studies to illuminate the complexity of factors that influence medication errors. The literature review found that the factors that contribute to medication errors are complex and multi-faceted, but could be divided into two subgroups: those caused by system errors and those caused by individual health care professionals.

A number of authors describe the individual, person focussed approach to addressing medication errors as ineffective (Brady, Malone and Fleming, 2009, Williams, 2007, Anderson and Webster, 2001). In common with administration of anti-D Ig, the process for drug administration is most often multi-professional and multi-factorial. The complexity of the process is regarded as a significant reason why focussing simply on the person who made the mistake is unlikely to lead to effective understanding of the error. Williams (2007, Pg344) states that 'the multiple steps in the medication chain, from when a drug is prescribed to when a patient receives the drug, leads to significant scope for error'. Instead authors advocate a multi-disciplinary approach that adopts an attitude of 'no blame' (Williams, 2007, Anderson and Webster, 2001) to encourage reporting of errors, followed by an approach to understanding errors that encompasses a systems approach (Williams 2007, Anderson and Webster, 2001). Brady, Malone and Flemming (2009) also note that system errors that contribute to medication errors transcend all professional disciplines and advance beyond professional or departmental boundaries. They too advocate a system-orientated approach to instigate procedures and put in place checks and balances to reduce or prevent medication errors. This reflects the work of Anderson and Webster (2001) who consider that a successful incident reporting system is central to implementation of an effective systems approach to drug error reduction. They go on to describe re-design of the clinical environment as key to both facilitating nursing duties and removing potential for error. However they reiterate that this is only possible once it is well understood how the system is going wrong: information gained through effective incident reporting.

Brady, Malone and Flemming (2009) found that nurses' knowledge was another significant factor in medication error. They note that the administration process requires nurses to 'engage with professional judgement and critical thinking to observe patients, communicate with all stakeholders, interpret relevant data and apply knowledge and experiences to specific patient situations (Pg 692). In one of the studies that they reviewed, nurses' lack of knowledge and experience was the cause of 79% of errors (Taxis and Barber 2003). These findings reflect those of other

literature which raise the issues of nurses and midwives knowledge and judgement as contributing as an important factor in the process of administration of drugs and the prevention and recurrence of errors (Karavasiliadou and Athanasakis, 2014, Birch and Culshaw, 2001). It is of note that some of the specific issues highlighted in relation to lack of knowledge during medication errors may not be directly relevant when considering the evidence in relation to administration of anti-D Ig: for example confusion over drug names and errors in calculation of dose. However other errors including inadequate safety knowledge, inappropriate selection of product and decision making in relation to drug administration are all factors that are relevant when considering administration of anti-D Ig. This is of particular note as a number of authors have suggested that knowledge and understanding of health care professionals may be a contributing factor in failures of care concerning women with an RhD negative blood type (Vause, Wray and Bailie, 2000, Howard et al, 1997, Van Dijk, 1997, Ghosh and Murphy, 1994).

The literature on medication error is important and relevant when considering error in relation to anti-D Ig, particularly as there is little evidence available to inform about factors that impact on anti-D Ig errors.

3.4 Informed decision making

As described above, clinicians' lack of knowledge and understanding of the issues involved may contribute to failures in care for RhD negative pregnant and postnatal women. Clinicians, midwives in particular, also have a substantial role in providing information and education to pregnant women. If knowledge of issues affecting pregnant RhD negative women is lacking in the health care professionals who provide information, this has serious implications for informed decision making and RhD negative pregnant women's ability to assume responsibility for their own health.

Van Dijk (1997) suggests that lack of compliance with current guidelines highlights lack of knowledge and understanding of issues surrounding anti-D Ig administration, not only among health care professionals, but also among RhD negative women. If

anti-D Ig is to be offered and administered within 72 hours of a potentially sensitising event then RhD negative women must be able to recognise such an occurrence and actively seek professional advice. There is some evidence that women's lack of knowledge and understanding of the issues involved may prevent them from seeking appropriate advice when PSE's occur.

Although it is widely acknowledged that many women do not understand the implications of routine antenatal screening tests for conditions such as Down's syndrome (Lee, 1998), there is little information about women's understanding of the implications of being RhD negative (Benbow and Wray, 1999). Several authors have speculated that women's understanding of the issues involved is poor and question whether women are fully aware of the implications of being RhD negative and pregnant (Wickham, 2001, Wray, 2000).

Vause, Wray and Bailie (2000) reported that evidence of poor compliance with guidelines for the management of RhD negative women shown in their study, may have occurred in part due to women not reporting bleeding, falls or trauma. In 45 (16%) of 282 identified potentially sensitising events in pregnancy, women did not seek advice from maternity care staff within 72 hours of a potentially sensitising event (Wray, 2000). The study was not designed to explore pregnant women's understanding of the impact of being RhD negative, or whether they felt informed about the issues. However Wray (2000) considering these findings, states that

> "The relationship between information giving, women's understanding of RhD negative status and the management of potentially sensitising events in pregnancy could be explored further".
>
> Wray (2000, Pg28)

Ghosh and Murphy (1994) also suggest that a major reason for non-compliance with clinical guidelines is that women, and/or healthcare professionals, have not recognised the implications of antepartum haemorrhage and Van Dijk (1997) suggests that preventing maternal sensitisation requires education of both professionals and RhD negative women.

Informed decision making is an important aspect of quality care. The Royal College of Midwives (RCM) noted the significance of informed choice in relation to anti-D Ig when the recommendation for RAADP was first made (RCM, 1999), and this is reiterated by the National Institute of Clinical Excellence (NICE) who make several statements and recommendations that reinforce the importance of informed choice in relation to RAADP within the guidance (NICE, 2002). The Royal College of Obstetricians and Gynaecologists (RCOG) Green Top Guideline (RCOG, 2011) also highlights the importance of information giving and informed decision making in relation to anti-D immunoglobulin.

The chances of an individual woman benefiting from RAADP are small, and only those women who have a partner with an RhD positive blood group and who go on to have a subsequent pregnancy will have any potential benefit. Anti-D Ig, a human blood product, is not without risk and those risks are complex and difficult to quantify. These factors combine to make it important that women make a decision about RAADP based on their own circumstances and their personal attitude towards potential risks and benefits. Facilitation of informed decision making, however, requires knowledge of all the issues involved, highly developed interpersonal skills and the time to spend in discussion with women on a one to one basis.

With the large number of decisions to be made and the rising number and sources of evidence for increasingly complex interventions, there are some authors who question whether patients actually want to make choices about their care (Rowbotham, 2005). Within the medical profession, there is a growing debate about the appropriateness and achievability of informed decision-making in the clinical setting (Davies, 2005). Being able to make informed decisions about care is a cornerstone of midwifery care, and Cooper (2001) believes that good midwifery care empowers women and involves respecting them, giving them information and offering them choice. By engaging a woman in the decision making process and by taking into account her personal values and individual circumstances better decisions will be made: for example an RhD negative pregnant woman who knows that the

father of her baby is also RhD negative will have no benefit from anti-D Ig as their baby must also be RhD negative.

Maternity care differs from other aspects of medical care: the population is unique in that they are, on the whole, healthy individuals making decisions without the added pressure of serious illness. Pregnancy and birth can be regarded as social events as well as physiological processes and, unlike most illnesses, are something that most women expect to experience at least once during their lifetime. As such decisions are made in a social context and may involve discussions with friends, family and acquaintances who have been, or expect to be, faced with similar choices. The context within which maternity care is delivered has changed greatly in recent years. Government policies that advocate choice and control for women (Maternity services action group, 2011, DoH, 1993), growth of organisations such as the National Childbirth Trust and much easier access to information through media and the internet have transformed women's expectations. Davis (2003, Pg 575) describes childbearing women as having moved from being "passive recipients of health care to the choosy consumers of health services". Hewson (2004) believes that this means that women are now more likely to question or even reject professional advice.

There is evidence that women's satisfaction with their maternity care is directly related to the quality of information they receive and that communication and information are regarded as top priorities (Benbow and Churchill, 2000). There is also evidence that women want information and choices in their care and there are well established links between perceived control and improved emotional outcomes (Kirkham, 2004) although much of this work is from large qualitative studies that focus primarily on women's choices concerning place and mode of delivery and the care they receive during labour.

Despite evidence that informed choice is both desirable and beneficial, within maternity care in the UK shared decision-making has been a relatively recent development. The medicalisation of childbirth was accompanied by development of a paternalistic relationship between healthcare professionals and patients: clinicians

regarded as having superior knowledge and making important decisions about healthcare on behalf of their patients. The shift towards shared decision making within maternity care in the UK was formalised with publication in 1993 of the 'Changing Childbirth Report' (Department of Health, 1993). Changing Childbirth was a wide-ranging paper which addressed key principles that underlie effective 'women-centred' care. One of those key principles was choice. The report advocated working in partnership with women and acknowledged the importance of engaging them in the decision making process, holding as its fundamental principle a woman's right to be in control of her care in pregnancy (Page, Phillips and Drife, 1997).

In 2003, 10 years after the publication of Changing Childbirth, its author Baroness Cumberlege wrote that she believed that it's key principles, including choice, had been widely accepted and incorporated into maternity care in throughout the UK and that a woman-centred approach was the core belief in terms of a patient-centred NHS (Cumberlege, 2003). Others, however, disagree and Kirkham (2004) goes as far as to assert that while

> "Informed choice is important in policy statements… it remains at the level of rhetoric and informed compliance".
>
> Kirkham (2004, Pg266)

There is published research evidence that informed decision making remains unusual in different aspects of maternity care: Wiggins and Newburn (2004) conducted qualitative research to explore barriers to the facilitation of informed decision-making and found that the women in their study felt that they had little control over decisions that impacted their care during labour and delivery; Lee (1998) found that many women do not understand the implications of routine antenatal screening tests for conditions such as Down's Syndrome; and Pilley Edwards (2004) identified limitations within decision making about home births and inadequate choices. There remains, however, little information about women's understanding of the implications of being RhD negative (Benbow and Wray, 1999). Some authors have discussed this issue, with Wickham (1999a) questioning the quality and accessibility

of information available about anti-D Ig for pregnant women with an RhD negative blood type, Wickham (2001) and Wray (2000) also speculate that women's understanding of the issues involved is poor, and question whether women are fully aware of the implications of being RhD negative and pregnant.

The evidence described earlier (Pg 28-29) suggests that women do not understand the significance of being RhD negative and that this may impact negatively on the care they receive. Much of that evidence was published before the NICE guidance for routine antenatal anti-D Ig prophylaxis and there remain important unanswered questions about the decisions women make about anti-D Ig: Do women make a choice about this routine intervention? Do midwives assume that they will want this product? Are they aware that it is a blood product? (Wickham, 1999a) Several authors have speculated that RhD negative women are not encouraged to make decisions about their care although there is little research evidence to support this (Wray, 2000, Wickham, 1999a, Stewart, 1999, Saha, 1998). Stewart (1999) admits that a typical conversation about postnatal anti-D Ig would be along the lines of "You are rhesus negative. If you have a Rhesus positive baby you will need anti-D" and Wray (2000) suggests that midwives must ask themselves some questions about the care they provide for RhD negative women including

> "Are women fully aware of the implications of being RhD negative and what this means?" *and* "Do they know about the management of their care?"
> (Wray, 2000, Pg 27)

Much of the evidence concerning women's understanding of issues surrounding being RhD negative and pregnant is anecdotal.

There is some evidence that the subject is not discussed with women who receive anti-D Ig. Obstetrician Saha (1998), in a letter to the British Medical Journal, describes an adhoc survey of women attending her antenatal clinic. Of twelve women who had received anti-D Ig, none were aware that it was a blood product. This letter prompted Wickham (2001) to conduct her own adhoc survey of 8 obstetricians. None

of the obstetricians approached reported making any effort to ensure that women received information about potential risks of anti-D Ig. Seven of them felt that "women should not be made to worry about such issues" (Wickham, 2001, Pg35). Wickham (2001), also conducted research exploring the subject of anti-D Ig in midwifery and reports being contacted by 19 RhD negative pregnant women who obtained her email address through British and American consumer organisations (Wickham, 2001). Of the women who contacted her, she reports that none felt that they had received adequate information from their caregivers, and several stated that they did not realise that they had a choice about their management.

Wickham (2007) highlights the fact that around 40% of RhD negative pregnant women will be carrying an RhD negative baby, and so not at risk of sensitisation. She questions whether midwives should be engaging with women to further discuss all the available options, such as paternal blood typing in order to help establish fetal blood type. Other factors such as whether the woman plans to go on to have another baby may also influence her decision whether or not to have anti-D Ig.

3.4.1 Factors that affect provision of informed decision making

There are many factors that influence the provision of informed choice including organisational factors, culture, individual opinions and attitudes, and provision of written information.

a) Organisational and Cultural Factors

Many authors and commentators consider that organisational factors, on both a local and national level, influence both the availability of choices and the way in which options are presented. There are two main organisational factors that will influence the facilitation of informed choice in maternity care: the availability of treatment choices and the culture within which medical staff and midwives offer choice.

Within the UK evidence based practice has become an accepted standard and is widely supported by government policy. Initiatives such as National Institute of Clinical Excellence (NICE), in England and Wales, and Healthcare Improvement

Scotland (previously Quality Improvement Scotland), as well as specialist colleges and working parties such as the Royal College of Obstetricians and Gynaecologists (RCOG) and Royal College of Midwives (RCM) offer recommendations for practice based on review of scientific and clinical evidence, often also considering social and economic factors, to present guidelines for best practice. While the underlying principle of evidence-based care is considered fundamental to the process of informed decision-making, Karwalish, Fox and Pearlman (2002) note that the move towards providing evidence-based practice has changed the whole notion of informed consent. Evidence-based recommendations, such as RAADP, typically reflect decisions based on a population perspective, rather than on individual patients. This provides a juxtaposition where informed decision-making involves presenting a range of options tailored to an individual patient, but evidence-based guidance tends towards the opposite: that for each clinical situation there is a single 'optimum' solution.

If clinicians are to offer truly informed choice regarding an intervention they must have the knowledge, communication skills and confidence in their own practice to present women with options. Kirkham (2004) suggests that this level of patient partnership would in fact require a massive cultural change within maternity services: changes in power relationships and in the organisation and delivery of maternity care. Facilitation of informed decision making is heavily influenced by the context within which healthcare is currently delivered. Kirkham and Stapleton (2004) describe conducting a major piece of qualitative research involving women and healthcare professionals at three maternity units in England and Wales. The research involved observation of 886 antenatal consultations and 383 interviews. The majority of health professionals were midwives. The research describes an organisational structure in which senior medical staff who defined norms of practice and what choices were available. Kirkham and Stapleton (2004) observe that the women in the study largely conformed to what was expected of them and remained passive recipients of maternity care rather than partners.

Davis (2003) describes some technological interventions as having become routine practice and often not presented as choices at all. Piley-Edwards (2004) conducted qualitative research of 30 women's experience of planning home births and described a situation where midwives were in an impossible position of ensuring that women accepted care in line with medical policies, but were also compelled by an obligation to offer choice. This led to a culture of 'telling not listening' where

> "Informed choice means informing women so that they will choose the choice being advised and differences in opinion indicate a lack of understanding on the part of the women"
>
> (Piley-Edwards, 2004, Pg 12/13).

Davis (2003) argues that society's propensity toward victim blaming also serves to press women toward medical and technological interventions so that the 'choices' we suggest she has are not really choices at all. This reinforces the notions of 'right' and 'wrong' choices as opposed to informed choices. This may not be limited to pregnant women, in Kirkham and Stapleton's (2004) research, fear of litigation on part of clinicians was also seen as a major influencing factor determining the way in which choices were presented to, or withheld from, service users.

Other organisational factors such as: lack of continuity of carer, as midwives have to establish an effective relationship with women at each appointment; situations where women and midwives come from different social and/or cultural perspectives; work pressures such as time available for discussion; and local variations in options available, have all been seen as distancing health professionals from childbearing women and impeding women's ability to make informed decisions (Kirkham and Stapleton, 2004 and Charles, Whelan and Gafni, 1999).

b) Individual midwives' influence

While cultural and organisational factors influence the choices available and the context within which they are offered and considered, the influence of individual practitioners on provision of informed decision-making is also evident. It is acknowledged that pregnant women have individual biographies, come from

different contexts, have different abilities and concerns and constraints –all of which affect the decisions they will make. It should be acknowledged that clinicians too are individuals and are influenced by the same factors, inevitably influencing the choices they offer and the context in which they present them.

Boyd et al (1999) asked ten midwives who had offered antenatal HIV testing to a total of 2727 pregnant women to complete a questionnaire aimed at eliciting their knowledge of and attitudes towards HIV. They found that the midwives' level of knowledge was not associated with uptake of testing, but that the midwife who had the most positive attitude towards HIV also had the highest uptake of testing and caused the women she offered the test to the least amount of anxiety.

Levy (2004) undertook a grounded theory study of the processes involved when midwives facilitate and women make informed choices during pregnancy. Twelve midwife booking appointments were observed, with the midwives and the women subsequently interviewed separately. The authors then observed further interactions between the midwife/women pairs, for example home visits and appointments later in pregnancy. Data were analysed using a grounded theory approach, identifying two theoretical frameworks describing the processes of facilitating and making informed choices during pregnancy from the midwives' and women's perspectives. Levy found that midwives regarded facilitating informed choice as an essential part of their job and that they, as individuals, had a major influence on the choices offered to women and the way in which those choices were presented. The research highlighted a balance that midwives felt they had to strike between giving a woman enough information and frightening her. This was compounded by a desire to meet the needs of the women while acknowledging their own strong feelings about certain issues. Levy (2004) concluded that facilitating informed choice is a

> "Highly complex activity, demanding of the midwife great sensitivity and personal awareness, as well as highly developed personal skills and knowledge".
>
> Levy (2004, Pg 70)

Kirkham and Stapleton (2004) also highlight midwives' individual influence on decision-making. They report that midwives were observed withholding certain leaflets because they contradicted their personal philosophy, customary clinical practice or because they conveyed a 'negative' image. During the same research clinicians were frequently observed framing information in such a way as to 'steer' women towards making decisions that reflected the point of view advanced by the health professionals.

c) Provision of written information

For pregnant women the antenatal period is a time when there are a large number of decisions must be made. For midwives it is a time during which they must impart a large amount of information, establishing appropriate and efficient means of communication in order to do so effectively. As pressures on time available for antenatal appointments and the number and complexity of issues for which decisions need to be made increase, clinicians are ever more dependent on written patient information.

A Cochrane review of decision aids for people facing health treatment or screening decisions provides a systematic review of randomised trials of patient decision aids in improving decision making and outcomes (O'Connor et al, 2007). The original review was completed in 1999 with the most recent update in 2004. There were 17 studies focusing on 11 different screening or treatment decisions included. The review found that decision aids do a better job than usual care in improving patients knowledge about options, reducing their decisional conflict and stimulating them to take a more active role in decision making without increasing their anxiety (O'Connor et al, 1999). It also showed that decision aids had a variable effect on the decisions that were made and virtually no effect on satisfaction with care.

There have been some studies that consider the role of decision aids within a maternity care setting. Soltani and Dickinson (2005) conducted an evaluation of the role of information plays in informed choice and decision making in routine clinical practice. They surveyed all women who gave birth at their maternity unit during a

three month period (n=700) with a 47% response rate. The women stated that their preferred methods of receiving information were one to one discussion and leaflets, with both methods preferred by over 70% of women (the questionnaire gave multiple choice answers and an option to tick more than one answer). Ninety two per cent of the women who responded stated that they read most or all of the information given to them, with 54% of women stating that they understood all information provided, and a further 43.5% stating that they understood most of it. One of the most important limitations of this study is the potential bias for self-selection to complete the forms by those who were more likely to understand both the questionnaire and the information they were being asked about. It may be that the proportion of women not understanding written information is in fact higher than suggested by this study.

Much of the research evidence surrounding written information provided to pregnant women concerns the 'informed choice' series of leaflets produced by the Midwives Information and Resource Service (MIDIRS). Launched in 1996, the leaflets aim to provide an objective appraisal of scientific evidence and examine key decisions facing expectant mothers, designed to assist them in making informed choices. The leaflets are produced in consultation with consumers groups, are peer reviewed and are supported by both the Royal College of Midwives (RCM) and the National Childbirth Trust (NCT). The series includes 21 topics and covers all topics specified in the Clinical Negligence Scheme for Trusts maternity standards and they are reviewed on a biennial basis.

Oliver et al (1996) report a case study based on observations from their pilot study of the MIDIRS informed choice leaflets on routine ultrasound scanning. At two of the hospitals where the leaflets were to be piloted ultrasonographers reported serious concerns that the information within the leaflet would cause severe anxiety for women and may lead to a reduction of uptake for ultrasound scanning and disruption to the hospital organisation. This led to the withdrawal of one of the hospitals from the pilot study. In fact the leaflets were received favourably by the women and their midwives at the hospitals that participated and ultrasonographers reported very little

feedback or concern as a result of their use. This study appears to reiterate the resistance of some healthcare professionals to providing detailed written information for fear of causing anxiety. In discussing their findings Oliver et al (1996) consider that the call for more choice has not been accompanied by corresponding investment in training professionals, or in organising the health care process to make time and provide facilities for promoting more active participation by healthcare users. However this paper is now is now over 10 years old and it may be that attitudes have changed.

The only published evidence about the written information provided for RhD negative pregnant women comes from Wickham (2007) who describes conducting a 'brief study' of information leaflets Wickham (2007) questioned the quality and impartiality of the leaflets noting that: the majority were produced by pharmaceutical companies; they focussed on why anti-D Ig was important; they contained no mention of side effects; there was no suggestion that anti-D Ig was a choice and that they used simplistic language.

3.5 A policy perspective: pregnant and postpartum women with an RhD negative blood type

Maternity units in the UK were slow to implement the 1998 recommendation for routine antenatal anti-D Ig prophylaxis (RAADP). Although this could be explained in part by the significant financial implications associated with the policy, the recommendation had also raised other concerns. The main concerns were voiced by the Royal College of Midwives (RCM) who called for further review of the policy before it was implemented. The RCM had four major concerns about RAADP: the quality of the evidence used to support the policy; failure to address poor compliance with current {1991} guidelines; that women should receive the information necessary to make an informed choice; and the financial and resource implications of the policy (RCM 1999).

3.5.1 Anti-D Ig policy: midwifery perspective

Midwives have a key role in the identification of women for whom anti-D Ig is appropriate, facilitation of informed decision making about anti-D Ig and administration of the injection, particularly with RAADP which is often given during a routine antenatal appointment. However, midwives had extremely limited input to the expert reviews that led to the recommendation for a policy of RAADP in the UK. The key participants were scientists, haematologists and obstetricians.

When the RCOG consensus statement recommending RAADP for all RhD negative pregnant women in the UK was published, the midwifery profession questioned not only the scientific evidence for RAADP, but also whether an intervention such as RAADP, which is not completely without risk for mothers and babies, was the only and best approach to the problem. A routine policy offering one option for everyone was regarded by some midwives as at odds with a midwifery perspective that places emphasis on working in partnership with women to facilitate individual choices to suit individual circumstances. The 1998 RAADP recommendation led to significant professional debate, with the Royal College of Midwives (RCM) publishing an 'Anti-D Update' outlining concerns about the proposed policy and issuing guidance to its members that they should continue to comply with the current {1991} guidance (RCM 1999). The United Kingdom Central Council (UKCC: the UK nursing and midwifery regulatory body at the time) also questioned the policy, with a spokesman stating

> "We support its {anti-D Ig} previous use but are concerned that the product has not been tested properly for routine use. It is an unknown quantity."
> (Coombes, 1999, Pg7).

One UKCC member went as far as to state that "as a midwife in practice, I would advise women against the use of anti-D {RAADP}" and went on to express fear that midwives' jobs might be under threat if they refused to implement the new guidance (Coombes, 1999, Pg7).

Policy and Practice Concerning Women with an RhD Negative Blood Type: A midwifery perspective

The midwifery perspective on care provided for pregnant women with an RhD negative blood type differs significantly from that of the scientists and medical staff who have, so far, been instrumental in developing policy. Considering the issues from a midwifery perspective is important for two main reasons:

1. The midwives' roles and responsibilities in relation to the care of pregnant women with an RhD negative blood type, and the administration of anti-D Ig in particular, differ significantly from those of obstetric staff.

2. The midwifery profession has a unique underlying philosophy that influences policy and practice.

It is useful to consider the midwifery perspective within the context of maternity care in the UK and provide some background to midwifery culture and approach in the UK.

In the UK care for pregnant women is most commonly provided by midwives and obstetricians. Midwifery and medicine are distinct but complimentary and overlapping professions. Obstetricians are experts in pathology with primary responsibility for the care of pregnant women who have underlying illness or complications of pregnancy, midwives are regarded as experts in normal pregnancy with primary responsibility for the care of pregnant women with uncomplicated pregnancies. The two professions developed differently and traditionally have distinct approaches to the care of pregnant women, based on particular perspectives and with differing philosophies and focus (Rooks, 1999). The midwifery profession developed within a social context where women provided each other with support in times of need (Rooks, 1999; Silverton, 1993). In 1902 the Midwives Act established state regulation of midwives and the midwifery profession developed subsequently.

Silverton (1993) describes a 'medicalisation' of childbirth as having occurred in the UK since the 1960's, with a move towards hospital birth being the norm. Robinson (1989) suggests that this resulted in a loss of decision-making for midwives. It is true that today most women now give birth in hospital and the context within which

midwives practice has changed, however as the context of maternity care in the UK developed midwives also adapted. Yuill (2012) describes the move of midwifery education to higher education institutions in the late eighties and nineties as resulting in academic credibility and acknowledgement of midwifery as a profession. It also led to the midwifery profession having increased input to and influence on childbirth research, with establishment of midwifery Professors further enhancing this. Midwifery 2020, a key maternity care policy document describes a current model of care where most midwives now work within a hospital environment, maintaining their skills as the lead professional for healthy women with straightforward pregnancies, while developing new skills in caring for women with complex medical and obstetric complications (Department of Health, 2010)

The literature often describes a midwifery ‘model’. Van Teijlingen (2005) suggests that the term model is better replaced with ‘approach’ or ‘ideology’ and that it is often used to describe ways of practising as well as an overall philosophy or approach to care. Unsurprisingly the midwifery approach has its roots in feminism, in empowering women. Wickham (2001) describes aspects of the midwifery and medical models in Table 4 (below).

Table 4: Aspects of the medical and midwifery models from Wickham (2001)

Aspects of Approach	Medical Model	Midwifery Model
General View of Childbearing	Inherently risky, Abnormal	Normal life event/rite of passage, occasionally deviates from the norm
Focus Of Care	Safety, physical factors and measurements	Woman's defined, holistic needs
System of Care	Usually hospital based; routinisation/standardisation of care may occur	Usually community/home based care geared to individual needs
Dominant emotions	Fear	Trust respect for nature
Basis of evidence informing practice	Quantitative controlled trials, positivist methodology; proof	Qualitative, experiential, intuitive knowledge

Source: Wickham (2001, Pg5)

At its heart the midwifery approach to care regards pregnancy as "a critical, vulnerable, but normal part of women's lives" (Rooks, 1999, Pg 370) with the normalcy of pregnancy at the core of the approach. Whereas the obstetric approach often calls for treatment as a preventative measure, the midwifery approach recommends waiting until there is evidence that the intervention is needed. This can lead to situations where the medical and midwifery approaches to care conflict, and (Rooks, 1999) describes obstetricians as often using interventions to prevent or treat complications before there is evidence that they exist.

The aspects of the medical and midwifery approaches described above, and in Table four in particular, are extremes and in reality very few midwives or obstetricians will

practice at those extremes. Midwives and obstetricians are individuals who work in diverse locations, organisations and cultures, even within the UK, and subsequently have diverse approaches to care. Although there are clear differences, and even some areas of conflict, between obstetrics and midwifery, there is also much common ground. In the UK today there is a wide spectrum of views and practice within both medical and midwifery practice and obstetricians and midwives most often work together. Rooks (1999) considers that the two models have merged somewhat with most midwives acknowledging the importance of medical treatment and most obstetricians recognising the importance of social and emotional aspects of childbirth. Current maternity care policy in the UK supports working in partnership with women to facilitate informed decision making and woman-centered care based on individual needs (Yuill, 2012, Maternity Services Action Group, 2011, Cumberlege, 2003). However, the extent to which midwives are willing and able to practice in such a way is disputed by some authors (Kirkham, 2004).

The use of anti-D immunoglobulin to prevent maternal sensitisation and subsequent HDFN is a good example of the ways in which the medical and midwifery professions work together to provide care for pregnant women. However it is also one where their different perspectives may cause conflicting opinions on best practice. Although the use of anti-D Ig following potentially sensitising events and delivery of an RhD positive baby has been an established aspect of medical and midwifery practice for many years, the 1998 RCOG recommendation for RAADP was challenged by midwives. The routine administration of anti-D Ig without recognised event or risk factor, typifies the juxtaposition between the medical and midwifery approaches to care. Medical and scientific support for RAADP might be regarded as an example of using a pre-emptive intervention to prevent a complication before there is evidence that it exists. While the midwifery profession called for examination of alternative approaches that might improve outcomes without giving all women anti-D Ig, the midwives viewing the evidence supporting recommendations as based on a potential population benefit rather than the benefit for the individual woman. Van Tiejlingen (2005) describes one of the characteristics

of the midwifery approach as being that each woman is considered an individual judged on her relevant strengths and weaknesses, rather than on a statistical chance of certain obstetrical and medical risks. This view is summed up by Savage (1986) who states that

> ”as the risks of childbirth become smaller statistical methods of predicting {poor outcomes}… have a limited use… if you look at each woman as an individual and plan her care with her, you will get the best result”
>
> Savage (1986, in Van Tiejlingen, 2005, section12.4).

Midwives also highlighted the importance of informed decision making in relation to anti-D Ig. Although this had been commented on in the RCOG recommendation (RCOG, 1999), midwives recognised the complexities involved and the implications for their practice in terms of facilitation informed decision making and in administrating the anti-D Ig itself.

In many aspects of maternity care, midwifery and obstetric practice and policy overlap. In the case of RAADP the medical and scientific professions worked together to make recommendations but in excluding midwives from that process they failed to recognise the significant input that midwives have in this aspect of care.

3.5.2 Anti-D Ig policy: scientific perspective

Sensitisation of RhD negative pregnant women occurs due to one of two reasons: failure to administer sufficient anti-D Ig in line with guidance; or as a result of silent sensitisation, sensitisation without any apparent outward event. Silent sensitisation is presumed to be caused by transplacental fetomaternal haemorrhage (FMH) and Urbaniak (1998) details a number of studies that demonstrate ‘occult’ FMH occurring in the absence of a precipitating event. Urbaniak (1998) describes the work of Bowman et al (1986), a study that involved 33 RhD positive volunteers who were subject to serial Kleihauer testing during pregnancy (Kleihauer test can be used to measure the presence of fetal red blood cells in maternal circulation, FMH). Bowman et al (1986) demonstrated that the rate of FMH increased as gestation increased, with

3% of women having FMH in the first trimester, 12.1% in second trimester, 45.5% in third trimester and in 63.5% an FMH was seen post-delivery.

It would appear that not all FMH lead to sensitisation since, although Bowman et al (1986) demonstrated the presence of FMH in up to 63.5% of pregnant women, the number of RhD negative pregnant women who become sensitised without any anti-D Ig prophylaxis is around 17% (Contreras, 1998). In Bowman's research, of the 15 women who were shown to have FMH in the third trimester, seven had an FMH of 0.02ml or less, seven 0.05ml to 0.3ml and one had an FMH of 5.15ml (Bowman et al, 1986). The volume of FMH required to cause sensitisation varies between individuals, with Urbaniak (1998) stating that as little as 0.1ml may cause sensitisation in a 'good responder'.

Routine antenatal anti-D prophylaxis (RAADP), the administration of anti-D Ig routinely to all pregnant RhD negative women, aims to protect against silent sensitisation. It does this by maintaining a prophylactic level of anti-D Ig in maternal circulation throughout the third trimester of pregnancy. Although RAADP might be expected to reduce the rate of sensitisation in RhD negative women, it will not prevent all sensitisations. Bowman and Pollock (1987) estimate that a residual sensitisation rate of between 0.24% and 0.31% should be expected even with the use of RAADP. This is because of inevitable failures to administer either antenatal or postnatal anti-D Ig in line with policy, and also because a small number of women will experience an occult FMH prior to administration of RAADP at 28 weeks gestation.

Much of the debate concerning RAADP centres on the scientific evidence of its efficacy. There have been no systematic studies to consider the reduction of mortality observed with RAADP (Urbaniak, 1998), despite Crowther and Middleton (2009, Pg5) stating that "the clinical benefit sought is the avoidance of haemolytic disease in subsequent babies". Instead, the evidence supporting introduction of RAADP centres on studies that use the rate of sensitisation of RhD negative women as an outcome measure. This is important for a two main reasons:

a) The Real Clinical Impact

Sensitisation in itself is not harmful, and the pregnancy during which a woman becomes sensitised is very unlikely to be affected by the red cell antibodies. The real impact of sensitisation comes if a woman has a subsequent pregnancy with an RhD positive baby and if that pregnancy is affected by haemolytic disease of the fetus and newborn (HDFN). Measuring sensitisation alone, particularly during the index pregnancy, does not tell us about the clinical impact of RAADP. A more pertinent outcome measure would be the number of women who go on to develop anti-D antibody during a subsequent pregnancy, and how many of those pregnancies are affected by HDFN.

b) Measuring Sensitisation

One of the most important issues when using sensitisation as an outcome measure is the timing of the test used to detect antibodies. Individual immune response varies greatly and it is known that while some women will have detectable antibodies during the sensitising (index) pregnancy, others may not have them until months after delivery and others still will not test positive for anti-D antibodies until they have a subsequent pregnancy with an RhD positive baby. Women who do not have detectable anti-D following the index pregnancy, but have a secondary immune response during a subsequent pregnancy are described as ‘sensibilised’. Studies that only test for sensitisation during pregnancy, or soon after delivery, may underestimate the true rate of sensitisation. The work of Bowman and Pollock (1978) suggests that even if women are screened at six to nine months following delivery, around 20% of cases of sensitisation will be missed. Chilcott et al (2004) acknowledge that studies that test for antibodies at only one point in time are likely to under estimate rate of sensitisation.

For the same reason testing during pregnancy is ambiguous since it is impossible to tell whether sensitisation is as a result of this pregnancy or due to a previous (perhaps unreported or unrecognised) pregnancy, or blood transfusion. In such a situation it is

quite possible that a woman who has been previously sensibilised would test antibody negative early in her pregnancy but as the fetus grows and her immune response develops, anti-D antibody will be detected during later tests. This is not due to a failure of prophylaxis during the current pregnancy as the sensitisation resulted from the previous index pregnancy.

Depending on sensitisation as an outcome measure raises another important issue. Laboratory testing is unable to distinguish anti-D Ig given during pregnancy, known as passive anti-D, from immune anti-D antibodies. Information about the date, time and dose of any anti-D Ig that has been administered is required in order to calculate whether anti-D antibody identified during testing is most likely passive or immune. The most recent SHOT annual report (Bolton-Mags and Cohen, 2012) describes seven reported cases where the laboratory assumed a positive antibody screen was due to passive anti-D (anti-D Ig), but babies went on to develop HDFN and the mothers were subsequently found to have immune anti-D antibodies. None of the studies concerning RAADP acknowledge the potential for false positive or false negative antibody screening test results, but it would seem that this could have significantly impacted on the reporting of sensitisation among the women in the study groups who received anti-D Ig during their pregnancies.

This raises an important question about the clinical relevance of the outcomes measured in all of the studies described below. Crowther and Middleton (1999) acknowledge that one of the most important areas still to investigate is the effect of antenatal anti-D Ig on subsequent pregnancies.

3.5.2.1 Formal review of the scientific evidence for RAADP

The first formal recommendation for a policy of RAADP in the UK came following a meeting of the Royal College of Physicians and the Royal College of Obstetricians and Gynaecologists (RCOG) at a consensus conference in 1997.

Nine clinical trials were presented as evidence at the consensus conference, with only the randomised clinical trial of Huchet et al (1987) considered of sufficient standard

to merit their 'Grade A' recommendation in terms of evidence-based research (Urbaniak, 1998). Huchet et al (1987) conducted a multi-centre randomised control study comparing the effect of antenatal prophylactic anti-D Ig administration on rate of sensitisation. One thousand eight hundred and eighty four RhD negative women from Paris and surrounding area were included in the study. Women were randomised with the study group receiving 500IU anti-D Ig, at 28 and then 34 weeks gestation, in addition to the standard postnatal dose. The control group received only the postnatal anti-D Ig, no placebo was used. The outcomes measured were rate of sensitisation during pregnancy and at 2-12 months following birth. The study showed a reduction in the rate of sensitisation during, or immediately after pregnancy from 1.02% (6/590) to 0.17% (1/599). One additional woman in the control group was found to be sensitised on testing at between 2 to 12 months following pregnancy. There was no significant difference in rates of neonatal jaundice between the groups. No data were available to assess rates of sensitisation or of HDFN, during any subsequent pregnancy, a major limitation of this study. As already discussed limiting testing to the current pregnancy and postnatal period will almost certainly underestimate the number of women who have become sensitised. The small numbers involved in this work, mean that only a few more women would need to test as antibody positive in a subsequent pregnancy to alter the significance of the findings.

Although the 1997 consensus conference report acknowledged that Hutchet et al (1987) was the only clinical study of adequate scientific merit, they pronounced that "the total body of evidence is compelling" (Urbaniak, 1998, Pg11). The outcome of the consensus conference was a recommendation, in 1998, for RAADP to be offered to all RhD negative pregnant women in the UK. Following this, Crowther and Middleton (2009) conducted a systematic review of the Cochrane Pregnancy and Childbirth Group's Trials Register, with the objective of 'assessing the effects of antenatal anti-D immunoglobulin on the incidence of Rhesus D alloimmunisation when given to Rh-negative women without anti-D antibodies'. They found only two trials that met their inclusion criteria and described them as of 'average to poor

quality'. Huchet et al (1987, described above) was one and the other was a UK study by Lee and Rawlinson (1995). Lee and Rawlinson recruited 2541 RhD negative primigravid pregnant women: 1273, the study group, received 250IU anti-D Ig at 28 and 34 weeks gestation and 1268, a control group did not. Data were incomplete for 469 women (205 in control group and 264 in treatment group) and a further 52 women in the treatment group did not receive both doses of anti-D Ig and so were excluded. Of the 2020 women remaining, 1108 gave birth to RhD positive babies and had test results for anti-D antibodies at the time of delivery and at six months postpartum available. Crowther and Middleton (2009) report that when the data from these two studies are pooled findings

> "Suggest a trend to reduced incidence of sensitisation during pregnancy (RR 0.42, 95% CI 0.15 to 1.17; 3902 women) after birth of a RhD positive infant (RR 0.42, 95% CI 0.15 to 1.17; 2297 women) and within 12 months following birth of an RhD positive infant (RR 0.41 95% CI 0.16 to 1.04; 2048 women)"
>
> Crowther and Middleton (2009, Pg5)

Both of these studies use rates of sensitisation during or just after pregnancy as their outcome measure. Neither considered sensitisation in subsequent pregnancy or rate of HDFN and as a result may underestimate true impact on clinical outcomes.

Another point of note is that Lee and Rawlinson (1995) excluded those women who did not receive both doses of anti-D Ig. Failure to administer some RAADP would be expected in any maternity unit and should be included in study findings order to reflect the true clinical impact of any programme of RAADP. The revised consolidated standards of reporting trials (CONSORT) statement notes the importance of including all participants in analysis, on an intention to treat basis. The group states that failure to do so may lead to erroneous conclusions (Altman et al (2001). It is likely that exclusion of those women who do not receive RAADP, because of system failures or their own refusal, will lead to over estimation of the true impact of a policy of RAADP.

Crowther and Middleton conclude that the quantity and quality of the available evidence for such an important question is disappointingly low, but state that the reduction in sensitisation rate is consistent with that seen in non-randomised trials. They state that because

> "Anti-D Ig does not appear to be harmful, antenatal prophylaxis is likely to decrease the number of sensitisations, without adverse effects and should be considered"
>
> Crowther and Middleton (2009, Pg5).

They also note that further trials are warranted to determine the optimal timing, number of treatments and effective dose, and reiterate that one of the most important areas to investigate is the effect of RAADP on subsequent pregnancies.

Around this time the Royal College of Midwives (RCM) stated its intention to lobby the Department of Health to ensure that the National Institute of Clinical Excellence (NICE) reviewed the evidence before any changes were made to anti-D Ig policy. In 2001 the National Institute for Clinical Excellence (NICE) did commission a systematic review of available evidence for the clinical and cost effectiveness of a community based programme of routine antenatal anti-D prophylaxis citing

> "The lack of clarity concerning the available evidence for RAADP, and consequent ambiguity of guidance supporting its introduction"
>
> Lloyd Jones et al (2004, Pg892).

Lloyd Jones et al (2004) conducted the review on behalf of NICE and found 599 potential articles of which ten studies, reported in 11 articles, met the inclusion criteria. These were all included in the review despite "considerable variation in design, quality, patient selection criteria, dosage, administration schedule and choice of outcome measures" (Lloyd Jones et al, Pg 893/894). The authors describe a host of factors that might influence the findings including the use of non-contemporary or geographically distant controls: creating potential bias due to differing obstetric

practice and laboratory testing techniques and equipment. There was wide variation in the timing of testing for sensitisation, ranging from during pregnancy to two to 12 months post-delivery, with only five studies checking for sensitisation in a subsequent pregnancy and only three of those providing data for the control group as well as the intervention group. Many of the studies only reported results for those women who actually received the treatment and Lloyd Jones et al (2004) consider that by excluding those women who did not receive prophylaxis due to refusal or logistical failures, some of the studies overestimated the impact of a policy of offering RAADP.

The 11 studies reviewed by Lloyd Jones et al (2004) reported on 30,169 pregnancies of RhD negative women who gave birth to RhD positive babies, of whom 146 (0.48%) women became sensitised. There were 12,342 women in the control group, of whom 168 (1.36%) became sensitised. Lloyd Jones et al (2004) state that the two largest studies were of poor design: one using historical controls and the other comparing geographically distant areas. These factors may well have created bias through differences in obstetric practice and laboratory testing techniques over time and distance.

The NICE review was intended to determine the impact that a policy of RAADP might have in the UK and Lloyd Jones et al (2004) focused their review on two UK studies: Mayne et al (1997) and MacKenzie et al (1999). Mayne et al (1997) conducted a retrospective survey of routine antenatal anti-D Ig prophylaxis using historical controls. The study was conducted in Southern Derbyshire where an RAADP policy, 500 IU given at 28 and 34 weeks, had been implemented in 1990. The outcome measure was detection of anti-D antibody (sensitisation) during a subsequent pregnancy. The study found that 16/1426 RhD negative women who were pregnant between 1988-1990 became sensitised, compared with and 4/1425 women who were pregnant between 1993-1995 (the earliest that any effects of the RAADP programme might be detected). This is a decrease in sensitisation rate from 1.12% to 0.28%. The paper gives little detail about the study methodology other than that the pregnant RhD negative women were identified using the laboratory register

and no case note analysis was conducted. It is not clear from the paper whether the baseline number is the total number of RhD negative pregnant women who had first pregnancies or whether that figure represents the number having subsequent pregnancies.

There is a potential bias within this study through the use of historical controls. As already discussed obstetric practice changes with time and the authors of this study acknowledge that requests for anti-D Ig following other potentially sensitising events, such as vaginal bleeding, increased during this study. They believe this was due to heightened awareness among community midwives and doctors and regard this as a benefit of the RAADP programme and a reflection of the true impact such a programme might have in a clinical context. However it is not clear how long such heightened awareness might be sustained and what impact the progression of the policy into routine and mundane practice might have on the effect witnessed. It is therefore difficult to determine whether this is a true benefit of RAADP, and an important factor to consider within the findings, or whether it does instead add to the potential bias of using historical controls.

The other study considered by Lloyd Jones et al (2004) was that of MacKenzie et al (1999). This was a prospective study which was designed to determine the impact of RAADP offered to all nulliparous RhD negative pregnant women, using the outcome measure of sensitisation in a subsequent pregnancy. The study group were identified in Oxfordshire where RAADP, 500 IU at 28 and 34 weeks, had been offered to all women with no living children from April 1986. The control group came from Northamptonshire where there was no such policy. The researchers used fortnightly laboratory serology meetings to prospectively identify all sensitised pregnancies where a woman was RhD negative and primigravid with an expected delivery date between 1987 and 1996. They then examined clinical notes to obtain details of both the current, sensitised, pregnancy and the previous pregnancy.

One potentially limiting feature of this study is that the researchers did not use actual pregnancies to determine the rate of sensitisation, instead the baseline ‘at risk’

number of pregnancies was estimated using national statistics. Data on annual maternities per health district and randomly selected local records were used to determine the numbers of births to nulliparous women and to women in subsequent pregnancies. National statistics on the mean interval between births per woman were also taken into consideration. The authors used these figures to calculate a sensitisation rate for 1980-1986 and 1990-1996 in Oxfordshire and Northamptonshire. The findings are shown in table 5 below.

Table 5: Impact of RAADP on sensitisation, summary of findings of MacKenzie et al (1999)

	Oxfordshire		**Northamptonshire**	
	Estimated at risk pregnancies	Sensitised Pregnancies	Estimated at risk pregnancies	Sensitised Pregnancies
1980-1986	2931	38 (1.3%)	3040	39 (1.3%)
1990-1996	3320	12 (0.4%)	3146	26 (0.9%)

It is unclear exactly how the use of an estimated number rather than an actual number of pregnancies to calculate a reduction in the rate of sensitisation might impact on the calculated sensitisation rate. However if statistics were collected in the two different regions in different ways, or if there were population changes over the time frame of the study that were not recognised and taken into account then an inaccurate baseline number of pregnancies could change the percentages involved quite significantly particularly when such small numbers of sensitised women are involved.

Comparing geographically remote groups also produces potential for bias. Obstetric practice may well have differed between the counties, and in fact the authors highlight that policy at the time did differ with Oxfordshire giving all RhD negative women anti-D Ig prophylaxis at delivery but Northamptonshire only giving it to

those women who delivered an RhD positive baby. It is highly likely that there were other difference in practice –both medical and midwifery- between the areas. Effective administration of anti-D Ig following potentially sensitising events during pregnancy requires a woman to recognise an event, seek appropriate timely help and attend a hospital or clinic. Different populations, logistics and organisation in the two different areas would impact on compliance with guidelines for administration of anti-D Ig.

Interestingly the number of sensitised pregnancies in the control group, Northamptonshire, also fell during the study period. The authors acknowledge that it is possible that RAADP might have been given in Northamptonshire without their knowledge, although they think this unlikely. Pregnant women and medical and midwifery staff are geographically fluid, likely to move between areas and to have conversations with peers and colleagues across the county boundaries. It would not be surprising if there was raised awareness in Northamptonshire of the use of RAADP in the neighbouring county and this may have influenced its use and of that of anti-D Ig following sensitising events, leading to a subsequent rise in administration of anti-D Ig and or increased compliance with guidelines, as has been demonstrated in other studies (Mayne et al, 1997).

Lloyd Jones et al (2004) describe these two studies as the best indication of the likely efficacy of a programme of RAADP in England and Wales, stating that their pooled findings suggest that RAADP could reduce the incidence of sensitisation from 0.9% to 0.3%. The strength of these studies lies in their analysis based on intention treat, they do not exclude the women who did not receive RAADP because of logistical failures of the system. Lloyd Jones (2004) also acknowledges the demonstrated reduction in sensitisations may not just be due to the anti-D Ig alone, citing Mayne et al (1997) observation that the policy may increase awareness of the need for anti-D Ig following potentially sensitising events during pregnancy. The results of these two studies indicate that the number of RhD negative women carrying an RhD positive child needed to treat (NNT) to avoid one case of sensitisation is 166, and as only 60% will be carrying an RhD positive child the actual NNT is 278. However the true

purpose of RAADP is to avoid HDFN and Pilgrim, Lloyd-Jones and Rees (2009) go on to calculate the overall NNT to avoid fetal or neonatal loss in a subsequent pregnancy as 5790. The NICE review concludes that widespread introduction of RAADP across the UK has the potential to reduce the rate of maternal sensitisation from the current estimate of between 1.2% and 1.8%, to around 0.35% (NICE, 2008).

The evidence described above was used to determine current policy for RAADP (NICE, 2002, RCOG, 1998) in the UK. Pilgrim, Lloyd-Jones and Rees, (2009) conducted a further review in 2007 in order to identify evidence for advances in the use of RAADP since the 2002 NICE appraisal. They found only one additional study and noted that it had similar limitations to those previously described.

In 2012 Turner et al conducted a further meta-analysis on the studies that had been examined by the NICE review. The Turner et al (2012) work differed in that it adjusted the meta-analysis for differences in study design and quality. They argue that this approach allowed new pooled results for the effectiveness of RAADP, based on synthesis of all evidence and taking into account any biases present in the design of all the trials (Turner et al, 2012). They conclude that their

> "Bias-adjusted synthesis of all available evidence provides strong evidence for the effectiveness of RAADP in preventing sensitisation, in support of the current UK policy of recommending RAADP to all non-sensitised pregnant RhD negative women"
>
> Turner et al, 2012, Pg 14).

There is also some emerging evidence about the efficacy of RAADP, with Davies et al (2011) conducting research to look at the protection that RAADP offers towards the very end of a pregnancy, the time when a significant silent FMH might be most likely to occur. They tested blood samples from 407 women who received two dose regimen RAADP and 157 women who received a single dose regimen RAADP. The research found that 160/407 (39%) and 123/157 (78%) of the women had no detectable anti-D Ig at time of delivery. There was an association between duration of pregnancy and detectable anti-D Ig at delivery: with women whose pregnancy

continued for more than 12 weeks following the last dose of RAADP less likely to have detectable anti-D Ig at delivery The authors did not follow the women up to determine the rate of maternal sensitisation or any subsequent HDFN, however they consider that for a significant proportion of RhD negative pregnant women, RAADP will offer limited protection towards the end of pregnancy.

The most important factor common among all of the research described is the use of maternal sensitisation as an outcome measure. There are no studies that tell us about the most important potential outcome of RAADP: its impact on HDFN. The limitations of using sensitisation as an outcome measure have been described, and are recognised by the authors of all three reports and reviews described here (Urbaniak, 1998, Lloyd Jones et al, 2004, Crowther and Middleton, 2009). The alternative of using HDFN as an outcome would require an extremely large multi-centre, possibly international, study in order to achieve numbers that might demonstrate effectiveness. Any such study would be further complicated by the need to span two or more pregnancies for each subject. As RAADP has now been implemented across the UK it seems unlikely that such a project will be undertaken.

As well as using sensitisation as the outcome measure, all of the studies presented as evidence of the efficacy of RAADP have important limitations: inappropriate control groups; factors out with the researchers control such as raised awareness of the condition and subsequent intervention; failure to test for anti-D antibodies in a subsequent pregnancy. Many of these are issues that are difficult to overcome when dealing with large numbers of study subjects all being cared for in a ‘real’ clinical setting by a number of different clinicians. However they are important limitations that may have significant impact on the study findings.

The reviewers all comment that the studies they reviewed all show a similar reduction in the rate of maternal sensitisation following the use of RAADP, citing this as evidence of its efficacy despite the limitations of the studies. In recommending RAADP as policy in the UK, all of the reviewers note the limitations of individual research studies, but describe a total body of evidence that points to a

reduction in sensitisation. They state that this, coupled with the perceived lack of potential harm associated with anti-D Ig mean that RAADP should be recommended.

3.6 Pregnant and parturient women with an RhD negative blood type: summary of key evidence

The overall aim of this research is to describe practice and policy surrounding the care of women with an RhD negative blood type, from a midwifery perspective. The specific aims of the three pieces of research that form this work are:

- To determine current UK policy in relation to the NICE (2002) recommendation for RAADP
- To describe anti-D Ig errors made by midwives
- To explore midwives' perspectives on the care provided to RhD negative women

As such, the literature was reviewed with the aim of providing understanding of the development of National policy and guidance, factors that impact the quality of care provided within those guidelines and to understand the midwifery context that impacts this area of clinical practice.

In particular the literature review highlights the links between the midwifery profession and development of policy and guidance surrounding care for RhD negative women. It is of note that following the 1998 recommendation for RAADP (RCOG, 1998) midwifery commentators voiced concerns that clinicians should explore gaps in practice and service delivery before implementing any changes to current anti-D Ig policy (RCM, 1999, Benbow and Wray1999). The decision to recommend implementation was based on scientific evidence for the efficacy of RAADP from a small number of studies that all have significant limitations in their methodology. Of particular note is the fact that although evidence suggests that introduction of RAADP will produce a small reduction in the rate of maternal sensitisation, it does not determine the potential impact on important outcomes such as reduction in the number of fetuses and babies affected by HDFN. Evidence

published prior to the recommendation for RAADP points to substantial failures in care for women with an RhD negative blood type. It is not clear from the evidence what contribution failure to address poor compliance with guidance around potentially sensitising events in pregnancy will make to continuing sensitisation and subsequent HDFN, nor is it clear what could be changed to improve practice and reduce preventable sensitisation. The NICE guidance recommending RAADP (NICE, 2002) led to widespread implementation of the policy and the impetus for reviewing and improving other aspects of practice appears to have been largely lost.

The literature review considered a number of aspects of provision of quality care for women with an RhD negative blood type. In particular midwives have highlighted the significance of informed choice surrounding anti-D Ig and RAADP more specifically. The evidence reviewed here highlights the complexity of the issues involved, in particular that an individual woman's circumstances can have a significant bearing on whether or not anti-D Ig is of any benefit to her. There is some evidence to suggest that midwives and medical staff may lack knowledge and understanding of the issues involved and as a result lack confidence in their own ability to offer informed choice in relation to anti-D Ig. The literature also suggests a culture within the NHS where midwives might find it challenging to offer women a choice about an intervention that is 'recommended policy'. Despite calls from the stakeholder organisations (RCOG, RCM, NICE) little information or additional resource has been made available to support midwives and medical staff in the facilitation of informed decision making around anti-D Ig.

The literature review uncovered an overarching theme that research, evidence and policy concerning care for women with an RhD negative blood group is led by medical and scientific staff, despite the fact that midwives are the main care givers in relation to anti-D Ig. This was highlighted as significant as the midwifery profession tends to consider issues from a perspective that those other professions might not. However, formal published evidence from a midwifery perspective is greatly under-represented in this field, meaning that a significant and important perspective on the

care of women with an RhD negative blood type is absent from the evidence base and subsequent policy and guidance documents.

The literature review demonstrates the need for systematic, good quality midwifery research in this area, reinforcing and justifying the stated aims of this research.

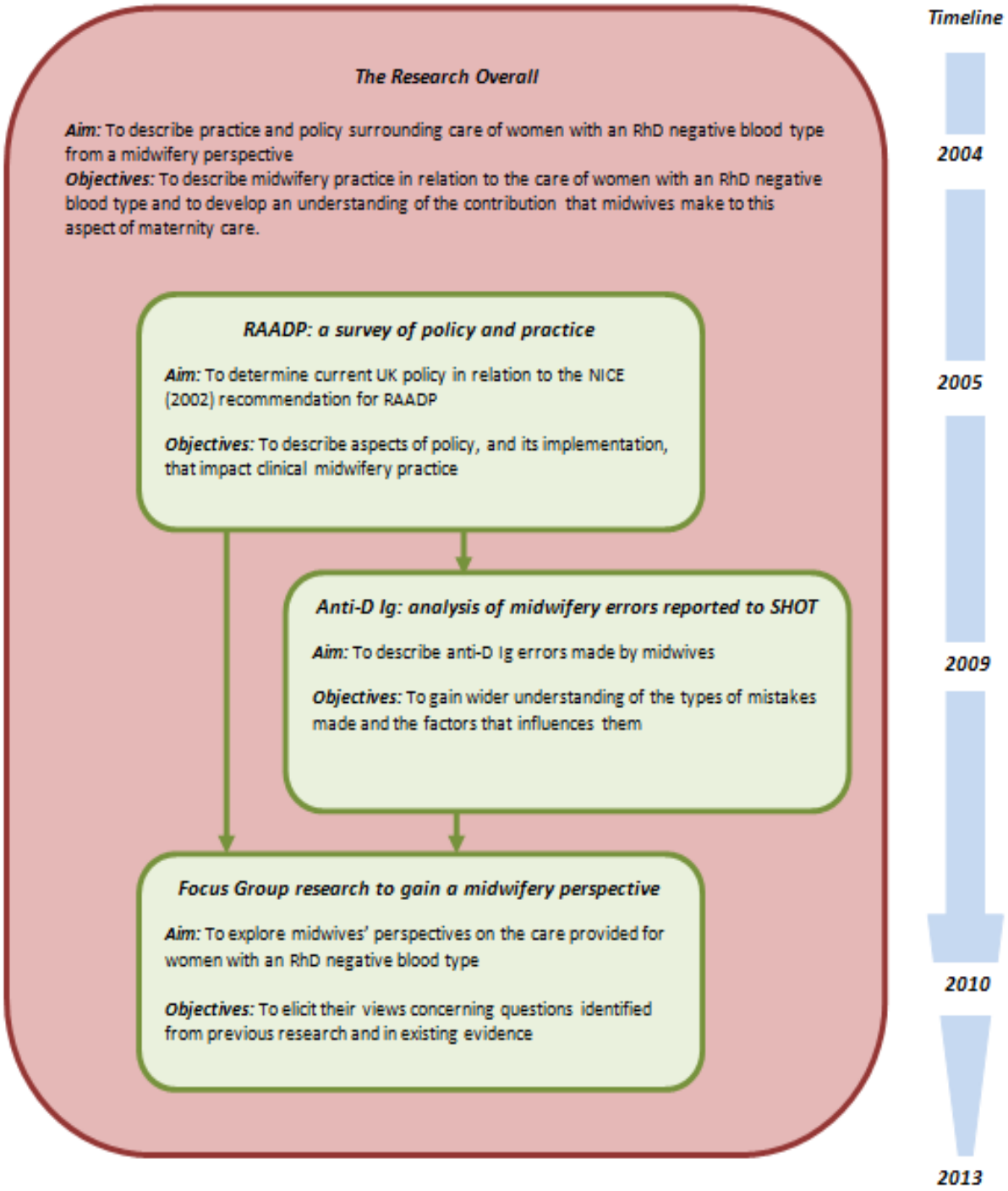
Chapter 4: Overview of design and methods used

This chapter provides an overview of the design and methods used and why they were chosen. More details of the methods and further rationale for choosing them are given in the chapters devoted to each of the pieces of research: Chapters five, six and seven.

4.1 Research design

The overall aim of this work is to gain a midwifery perspective on policy and practice in relation to women with an RhD negative blood type. The design was multi-faceted, using three distinct pieces of research. The three pieces of research, their aims and objectives, and the aims and objectives of the overall research are illustrated in Figure 2 below.

Figure 2: The research aims and objectives: individual phases and research overall



The use of three different methods of research was emergent, with each piece of research planned within the context of the findings of the previous. It is useful to consider how the research emerged and how the findings of each study led to development of the next.

The first piece of research undertaken was a survey of all UK maternity units to determine implementation of the NICE (2002) recommendation for a policy of offering RAADP to all RhD negative pregnant women. The survey found that implementation of a policy of offering RAADP was widespread throughout the UK, determining that for the majority of midwives offering and administering anti-D Ig was now integral to the antenatal care that they offered. The findings also raised questions about organisational impact on midwives ability to provide individualised, woman centred care.

Following completion of the RAADP survey the researcher had a two year break in studies. On returning to the work it was clear from personal experience that practice in this area had changed. For example, in Scotland the Scottish National Blood Transfusion Service (SNBTS) now only supplied single dose anti-D Ig for RAADP, and a new Scottish National leaflet, designed to support informed decision making for RhD negative women, had been made available to all Scottish maternity units. It was anticipated that practice in other parts of the UK in relation to the policy of RAADP were likely also to have changed and as a result it was deemed necessary to reconsider the nature of the subsequent research.

Around this time the researcher was working with colleagues from the Serious Hazards of Transfusion (SHOT) haemovigilance scheme on an unrelated project. This resulted in an opportunity to request permission to access the SHOT anti-D Ig error database, and subsequently to development of the subsequent research ‘Anti-D Ig: analysis of midwifery errors reported to SHOT’. This research was designed to explore midwives’ practice by identifying the type of errors that midwives make when offering and administering anti-D Ig. The findings of the analysis of the SHOT anti-D Ig reports raised further questions about the way that midwives practice and

the findings, alongside those of the RAADP survey and of the evidence discussed in Chapter three, were used as the basis for the third and final piece of research.

The researcher had always intended to gain midwives views through collection and analysis of qualitative data as this was deemed vital to the overall aims and objectives of the research. The intention of this third piece of work was to use focus group research to collect in-depth, qualitative data in order to elicit midwives views on care provide for women with an RhD negative blood type. It was intended that this qualitative data would both compliment and add depth to the information already gathered during the previous research.

The findings of the focus group research, alongside other evidence described in Chapter three, provided context within which to consider the overall work. The final part of the research process was to draw together the three pieces of research and discuss the findings in this context.

An overview of the specific aims, objectives, study designs and research methods applied to each piece of research are described below. The methods used are also described and discussed within each of the relevant chapters: five, six and seven.

4.1.1 RAADP: a survey of policy and practice in the UK

The aim of this piece of research was to establish current {2005} policy and procedures in the United Kingdom in relation to the National Institute of Clinical Excellence (NICE) recommendation for routine antenatal anti-D prophylaxis (RAADP) (NICE, 2002). The study design chosen was a cross-sectional descriptive survey.

Polit et al (2001) consider that survey obtains information about prevalence, distribution and interrelationships of variables in a given population. The method is one of self-report with respondents answering direct questions and although it is highly flexible the information gathered is relatively superficial. The survey design here was cross-sectional, that is data were collected at one point in time.

Survey design can be either descriptive or analytical. There are two aspects to examining policy and procedure; the policy documented and the application of this into practice. The focus of this survey was to document the policy, rather than actual practice. This included aspects of policy such as: whether RAADP was offered, whether written information was provided for the pregnant women and what, if any, midwifery education accompanied implementation of RAADP. In order to achieve a National (UK) picture of RAADP a descriptive survey design was considered the most appropriate method as its purpose is to "count, rather than to explain". (Oppenheim, 1992, Pg12)

Polit et al (2001) state that the three most common methods of collecting survey data are: personal face-to-face interviews, telephone interviews and self-administered questionnaires. The method of data collection deemed most appropriate for this project was a postal questionnaire. The wide geographical spread of the population sample meant that face-to-face interviews were not feasible. Structured telephone interviews were considered as an alternative to postal questionnaires for data collection. The advantages of conducting telephone interviews would have been ability to clarify questions, limiting misinterpretation of questions or answers. Interviews would also have given control over who provided the information. However, the intention was to survey the entire population (UK maternity units) rather than a representative sample. Given the large number, 348 units, limitations on time and resources available meant that a telephone survey was not possible.

Possible disadvantages of using questionnaires for this study were potential for low response rate, lack of control over who actually completed the questionnaire and no opportunity to check incomplete responses. These issues were addressed during the development of the questionnaire, and steps were also taken to maximise response rate, these are discussed in more detail in Chapter five.

In addition a request was made for a copy of any written patient information to be returned along with the completed questionnaires.

Survey data was analysed using the computer software package SPSS. The origin and content of the leaflets received was also analysed. The method used is described in further detail in Chapter five: RAADP: a survey of policy and practice in the UK.

4.1.2 Anti-D Ig: analysis of midwifery errors reported SHOT

The aim of this research was to describe anti-D Ig errors made by midwives. The objectives were to gain a wider understanding of the types of mistakes commonly made and what factors might influence those errors. It was also hoped that the findings would inform the next piece of research: focus group research to gain a midwifery perspective. The analysis of midwifery errors reported to the Serious Hazards of Transfusion (SHOT) scheme used a qualitative approach to conduct secondary analysis of existing incident reports.

Polit et al (2001, Pg469) describe qualitative research as "typically in-depth and holistic… using a flexible research design". Describing in detail the types of incidents and the factors that might influence their occurrence was the main aim of this research, and a qualitative approach allowed this in a way that quantification could not have. Another important advantage of a qualitative approach is that it can be emergent, evolving and developing as the work progresses (Polit et al, 2001). Although the research had clearly defined aims and objectives, the nature of the work meant that the most effective form of data analysis would be that which was led by the findings as they emerged, allowing further exploration of any emerging themes.

All recognised incidents involving anti-D Ig are submitted for inclusion in the Serious Hazards of Transfusion (SHOT) annual report. The published annual SHOT report contains summary data about categories of incidents and a small number of clinical vignettes describing actual incident reports. The researcher was granted access to all reports, in the anti-D Ig category, that had been submitted to SHOT for entry to the 2008 annual report. These were the full and complete reports as originally submitted to SHOT: data which encompassed all recognised anti-D Ig incidents that occurred in all UK maternity units during that time period.

As this research is about midwives, only those incidents that involved a midwife were included for analysis. A multi-layered approach to analysing the data was used, with the aim of describing the incidents in detail and identifying clinically relevant information that might allow a better understanding of why errors occur and what measures can be taken to prevent their recurrence

4.1.2.1 Simple classification of incident reports

Analysis began with simple classification and quantification of the incidents into broad categories. The classification mirrored the analysis performed by SHOT, but included only those reports where a midwife had been involved in some aspect of the incident. This was intended to provide information about the type and number of anti-D Ig incidents that involve midwives.

4.1.2.2 Detailed description of reports

The simple classification of incidents was followed by a more detailed analysis of the data that was based on critical incident technique. The aim here was to describe the incidents, identifying common themes and further categorising the data. It also allowed the identification of the proximal cause which had led directly to the adverse event.

4.1.2.3 Identification of key aspects of the reports

The final part of the data analysis was based on a framework that developed during this research. The method draws from Reason's model of understanding adverse events, an approach to analysing incidents that encompasses both a 'person' and a 'systems' perspective (Reason, 2000). Several authors now look beyond root cause analysis and many incorporate themes from Reason's model to develop a more integrated approach to analysing incidents. Such models include The London Protocol, a systems analysis of clinical incidents developed by Taylor-Adams and Vincent (2004).

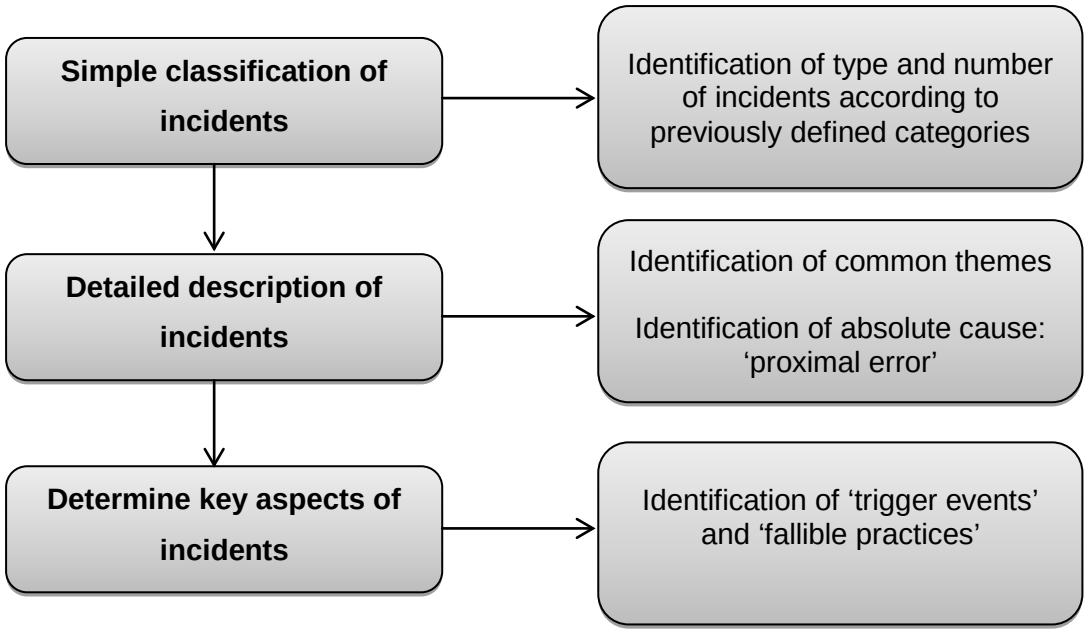
The approach used here was influenced by Reason's model and root cause analysis (RCA), but grew from and with this particular research. The result was a framework for analysis that was used to find the key aspects of the incident, those things that

directly influenced the errors. The framework identified that within the incidents there were three key aspects: a 'proximal error', 'trigger events' and 'fallible practices'.

4.1.2.4 An overview of the data analysis

The pathway of analysis of the SHOT reports is illustrated in Figure 3, below

Figure 3: Pathway of analysis of SHOT error reports



The methods of analysis: simple classification, detailed description of incidents and identification of proximal errors, trigger events and fallible practices, were connected and complimentary and intended to build detailed understanding of the types of anti-D Ig incidents that involve midwives, giving insight to common pathways that lead to errors and some of the factors that influence their occurrence.

The methods used are described in greater detail in Chapter six: Anti-D Ig analysis of midwifery errors reported to SHOT. That Chapter also gives more detailed description of Reason's model, root cause analysis and critical incident technique.

4.1.3 Focus group research to gain a midwifery perspective

The aim of this piece of research was to explore midwives' perspective on the care provided for pregnant women with an RhD negative blood group, with the objective of eliciting their views concerning the questions determined by the two pieces of research already undertaken. A qualitative approach, using focus group interviews was considered the most appropriate method.

This research aimed to elicit midwives' experiences, perspectives and attitudes as well as their ways of delivering clinical care. Porter (2000) states that qualitative research does not focus primarily on identification and explanation of facts, instead it can uncover the participant's interpretation of facts. As a result it is most appropriate for describing the understanding and motivations of the research subjects. The research was designed in context of that already undertaken (Chapters five and six) which had uncovered a number of issues and raised several questions about practice. An important objective of the research was to attempt to put these issues into the context of current midwifery practice, by listening to the midwives themselves in order to understand the context within which the issues arise and to uncover factors that might influence them.

The research method of choice was focus group interviews. Commonly focus groups are used to generate data or to test, for example a questionnaire to be used in a mixed methods approach. Kitzinger (1995, Pg299) describes focus groups as "a form of group interview that capitalises on communication between research participants in order to generate data". However here the group interviews were used primarily to elicit answers about data already generated from the 'real life' scenarios described in the SHOT incident reports and from the issues raised by the RAADP survey.

Alternative methods of data collection were considered. It would have been possible to conduct individual interviews, or even to use another survey, however an advantage of group interviews is that the process might help people to explore and clarify their answers and encourage participation from those who might otherwise feel they have little to say on the topic of discussion (Freeman, 2006). This was seen

as a major advantage as a key objective was to explore the context and the cultural and organisational factors associated with the topic, and neither interviews nor a questionnaire would have allowed respondents a full opportunity to reflect on their responses. In addition it was acknowledged that the midwives have major constraints on their time, affecting ability to organise multiple interviews. Using a group interview approach would provide a practical means of gaining the views of a larger number of midwives than might be possible through individual interviews, but with the advantage of gaining richer data than might be gathered through another survey.

The data analysis was also qualitative and is described in detail in Chapter seven: Focus group research to gain midwifery perspective.

In reality achieving answers to specific questions within the constraints of practical factors such as time available for focus groups (described in detail in Chapter seven) required the imposition of significant structure on both data collection and subsequent analysis. It could be argued that the imposition of that structure, in particular the adoption of structured data analysis, may have compromised the qualitative approach, with the substantive findings reflecting questions that had been predetermined.

In simple terms quantitative research can be described as focussing on numbers and qualitative research as focussing on words. However the methods are also understood to have more complex differences. Cormack (2000, Pg19) determines that qualitative research encompasses strategies that ‘seek to explain human behaviour in terms of the reasons people have for behaving the way that they do’. With Polit et al (2001, Pg208) considering the qualitative researchers generally ‘know what they do not know’ and qualitative researchers ‘don’t know what is not known’. As a result the first phase of many qualitative studies is to get a handle on what is salient about the phenomenon of interest. In this situation, the researcher already ‘had a handle’ on the salient points through conducting the previous research: the RAADP survey and analysis of the SHOT reports, and also from exploring existing evidence and literature.

The data collection method of choice was focus group research, a qualitative method (Kitzinger, 1995). In this case however, the structured nature of the data collection method meant that the method became more akin to semi-structured group interviews. Semi-structured interviews are also commonly considered to be a form of qualitative data collection however Porter (2000) warns that should they become too structured they risk reinforcing the researcher's assumptions. In such a situation it is important for the interviewees to have input outside of the pre-determined structure to maintain the ability to explore adequately their views without the researcher unduly influencing them. During the focus group interviews conducted here, although specific questions were asked, the subjects did have an opportunity to freely discuss those questions, generating a large amount of transcript. This meant that although the major findings do relate to themes that were predetermined, the focus group interviews also did also elicit data other than that set out within the remit of the structured data collection and analysis.

In reality both the data collection and analysis were influenced by the researchers established perspective: that is to a large extent 'she knew what she didn't know', a stance with more in line with a quantitative approach. The compromise in methods used was necessary in order to achieve the aims of the research within the constraints of conducting research within the real world of clinical midwifery. It did mean however that, although the research design intended to provide qualitative findings, the methods used incorporate aspects of both qualitative and a more quantitative approach.

4.1.4 The research as a whole

The aim of the study design overall was to gain insight to policy and practice in relation to the care of women with an RhD negative blood type, from a midwifery perspective. Careful consideration was given to what each of the three separate pieces of research contributed to the work as a whole in order to achieve this.

The aim of the RAADP survey was to determine actual implementation of a new recommendation. The survey formed the foundation on which to build the thesis by

determining whether RAADP had become an integral aspect of maternity care within the UK. The aim of the survey was to describe policy and not to explain findings, and so it raised important questions which were then used to inform the design of the subsequent research. The findings were also used to aid explanation of the findings of those research studies, Chapters six and seven. The second piece of research, secondary analysis of anti-D Ig errors involving midwives, identified both individual and organisational factors that impact occurrence of error. This piece of research also raised further questions about midwifery practice and those questions, along with those identified through the RAADP survey, formed the basis of the focus group research. The focus group research aimed to consolidate the findings of previous research by gaining direct input from midwives. This added substance to the findings of Chapters five and six and to the wider evidence base through investigation of the specific questions that had been raised by those pieces of research. It also allowed exploration of other aspects of care relating to women with an RhD negative blood type that emerged during the focus group interviews.

The final task of bringing all three pieces of research together to establish overall findings is undertaken in Chapter eight where they are discussed in the context of each other and of the wider evidence base.

4.2 Ethical considerations

Ethics is a philosophical approach that addresses morality and allows judgement about whether something is right or wrong. Polit et al (2001, Pg 461) define research ethics as “a system of moral values that is concerned with the degree to which research procedures adhere to professional, legal and social obligations to the study participants.” There are a number of high profile cases of serious breaches of ethical principles such as the Tuskegee syphilis study (William and Curran, 1973) and more recently at Alderhey, Liverpool, when it was discovered that the organs of children who died had been removed and retained without consent (Department of Health, 2001). The principles of modern day medical ethics have their roots with the 1947 Nuremberg trials and subsequent Declaration of Helsinki which has as one of its

fundamental tenants that researchers' primary ethical duties are to research participants and not to society. Within the healthcare setting a number of professional bodies have produced their own guidance on ethics, with the Nursing and Midwifery Council (NMC) producing 'The Code', a document that sets standards of conduct, performance and ethics for nurses and midwives. It is regarded as the foundation of good nursing and midwifery practice, and a key tool in safeguarding the health and wellbeing of the general public (NMC, 2008).

The ethical dimensions of a study are usually subjected to external review and Polit et al (2001) consider that this is crucial as it may be difficult for researchers to be objective owing to their desire to conduct a valid study. In the UK there is a requirement to gain ethical opinion for research within the NHS, and in Scotland the Chief Scientists Office (CSO) oversees this process via Research Ethics Committees (RECs). RECs provide independent advice on the extent to which proposals for research comply with ethical standards, and ethical opinion from the appropriate NHS Research Ethics Committee is required for any research proposal involving, among other criteria: Patients and users of the NHS; Access to data of past and present NHS patients; The use, or potential access to, NHS premises or facilities; NHS staff recruited as research participants by virtue of their professional role.

Within the context of the research as whole a number of ethical considerations were made. These included a commitment to publish and disseminate negative as well as positive findings, an open and consistent approach to the use of any statistical analysis in order to reduce potential bias, and transparency surrounding sources of funding and any potential conflicts of interest. The research as whole was undertaken with the intention of describing current practice, and the ultimate goal of being able to use the findings to inform future practice and policy. The study participants gave their time voluntarily on this premise and it was seen as an important to ensure that all steps were taken to disseminate findings and report back to those who participated.

Ethics were considered in relation to each of the three separate aspects of the project and within the context of the project as a whole. This was done within a framework of respect, confidentiality and non-harm and with consideration to the research governance framework and guidance provided by the CSO and NMC. In this thesis it was applied to each particular piece of research in the following ways.

4.2.1 RAADP: a survey of policy and practice in the UK

This piece of research was undertaken within the context of contemporaneous practice within the Better Blood Transfusion Programme at SNBTS, where survey work was regularly conducted to gather information about clinical practice in relation to blood transfusion throughout the UK. This does not usually require researchers to seek formal ethical opinion.

Although experience of previous similar projects suggested that a formal application to the Local Research Ethics Committee (LREC) would not be required, the researcher sought advice from the Chair of the Lothian Research Ethics Committee. The Chair was able to confirm that the project should be considered a service evaluation and as such did not require submission of a formal application for ethical opinion.

4.2.2 Anti-D immunoglobulin: analysis of midwifery errors reported to SHOT

The data for this research were collated by SHOT and provided to the researcher specifically for use in this study. Reports submitted to SHOT are provided on the premise that "SHOT undertakes research, studies and audit in the area of transfusion safety, and this may be solely, collaboratively or by commission." (Bolton-Mags and Cohen, 2012). As an employee of the Scottish National Blood Transfusion Service (SNBTS), and within the role of a specialist midwife, the researcher had legitimate clinical rights to access this database. As such the data were provided in original form and contained information that would allow identification of individuals and organisations. In order to maintain confidentiality, the data were scrutinised and any identifying information was removed. A new database containing the anonymous

reports was created, allowing the researcher to fully share and discuss the data with supervisors and advisors without compromising confidentiality.

4.2.3 Focus group research to gain a midwifery perspective

This research involved conducting group interview research with midwives. No patients were involved, but as the participants were NHS staff and sessions would take place on NHS premises, advice was sought from the South East Scotland Research Ethics Service (SESRES). SESRES requested submission of an outline of the project for consideration by the Scientific Officer. This resulted in advice that the research did not need NHS ethical review under the terms of the Governance Arrangements for Research Ethics Committees in the UK (Appendix 3). A copy of this letter was provided for the research governance teams at each of the participating NHS sites and no further action in respect to formal ethics review was required.

However, additional steps were taken to ensure that the midwives understood the implications of participating in this project. The midwives were invited to attend on a voluntary basis and prior to attendance they were given an information sheet outlining that: they would be participating in research undertaken as part of the researcher's PhD; the purpose and intended outcomes of the research; that the sessions would be audio taped to facilitate data analysis; that all information gathered would be anonymised and that after data analysis and write up were completed the audio recordings would be destroyed.

4.3 Funding and contribution of others

University fees were paid by the Scottish National Blood Transfusion Service and the work was completed in the researcher's own time alongside employment as a Transfusion Specialist Midwife.

The SHOT analysis was made possible through the willingness of SHOT to share the data they had collated. This was given freely and without condition for the purposes of the research as outlined to them.

Chapter 5: RAADP: a survey of policy and practice in the UK

5.1 Introduction

The aim of this research was to determine current policy in the UK in relation to the 2002 National Institute for Clinical Excellence (NICE) recommendation for routine antenatal anti-D prophylaxis (RAADP). This was achieved through a postal survey of all UK maternity units conducted in July 2005. A formal break in studies was taken following completion of this piece of work and the resulting time lag between its completion and subsequent write up resulted in this chapter being a summary of the research findings. The survey was published in Transfusion Medicine in 2008, (Harkness et al, 2008, *Appendix 1*), and was also mentioned in the NICE review of RAADP guidance in 2008 (NICE, 2008, Pg7, *Appendix 2*).

5.2 Methods

The reasons for choosing a cross-sectional descriptive survey are detailed in Chapter four, and it was recognised that within the chosen method there were a number of factors to consider in order to achieve the stated aims. Atkinson (2000) observes that a major challenge of survey research is to reduce the chance of the findings being wrong and this is can only be achieved through attention to the study design. Particular attention is required when considering: sampling error; non-response error and response error (Atkinson, 2000, Oppenhiem, 1992).

5.2.1 Population and sampling

Atkinson (2000) states that using a descriptive survey allows the researcher to make statements about a study population. The aim of this research was to make a statement about clinical practice regarding RAADP throughout the UK. It was important to determine exactly who the study population were. In the UK a particular NHS Trust or Board may have more than one maternity unit and it would not be unusual for those maternity units to have differing policies and procedures. For that reason the target population was defined as individual maternity units, rather than NHS trusts or boards.

The sample for this study was the entire population: that is all UK maternity units. Surveying the entire population might be seen as a method of eliminating sampling error, however (Oppenhiem, 1992) states that unless a survey is designed properly and aimed at the correct target population, even a whole population survey cannot be used to draw conclusions or make comparisons.

5.2.2 Response and non-response bias

It was identified that there was a need to reduce any bias through response and non-response errors. Non-response error occurs if decisions about whether or not to respond to the survey might be influenced by the respondents own behaviour. For example if a maternity unit does not offer care in line with recommended guidance, they might be less likely to respond. This leads to a potential for bias, in that an increased proportion of units that do offer RAADP might respond than those that did not, leading to an over estimation of implementation of the guidance. Measures were taken to reduce this bias by encouraging respondents to provide the information requested. These included: careful consideration about who should complete the questionnaire; clear explanation of the purpose and importance of the study; careful construction of the questionnaire to motivate response; and anonymisation of source of data/maternity unit.

Response error can be either random or systematic. In random response error there is usually a transcription or data entry error by the researcher. Atkinson (2000) believes that random response error does not usually cause bias as it will often correct itself statistically over the data field, that is a researcher would be just as likely to wrongly input a wrong ‘no’ answer as a wrong ‘yes’ answer. Measures were taken to reduce random response error through careful input of data and developing a system of random data checks. Systematic response error is potentially more likely to bias any findings. This type of error arises from the way data is measured or collected, for example through phrasing of a question at interview or questionnaire. The problem of systematic response error was carefully considered during construction of the questionnaire (section 5.2.3).

Another factor to take into consideration was who, within those maternity units, should be asked to complete the questionnaire. In order to limit the potential for response error, it was important that this was a person who was familiar with policy and procedure as well as the other issues that were to be addressed. Although the questionnaire primarily contained questions concerning RAADP policy, it also asked about information provided to RhD negative pregnant women and education provided for staff to support the implementation of RAADP. For this reason it was important that the staff member surveyed was a midwife, and that they were in a relatively senior position so as to be aware of policy. The person also needed to be closely associated with provision of antenatal care, surveying midwives who work solely on labour or postnatal wards for instance would not have been appropriate. For the reasons described, the person to whom the questionnaire was addressed was the 'senior midwife for antenatal care', likely to be the charge midwife in an antenatal clinic, or the midwifery manager responsible for antenatal care depending on the management structure of that particular maternity unit.

5.2.3 Questionnaire development and content

A questionnaire was developed specifically for this survey and contained questions that were based on the NICE recommendations concerning administration of anti-D Ig, information provided to RhD negative women and staff education and training. The questionnaire also included a request for a copy of any written patient information about RAADP. A copy of the questionnaire is included in Appendix 4.

A number of factors within the design of a questionnaire are recognised as influencing response rate. These include: relevance of topic; general appearance; length and ease of completion. Strategies within the construct of the questionnaire were developed in order to minimise the impact of these.

The first stage of the process of developing the questionnaire was to compile a list of the variables that were to be measured, and following that to consider the most appropriate types of questions or instruments, such as scales, to collect data that would allow accurate measurement of each of those variables.

5.2.3.1 Type of questions

A closed question is one in which the respondents are offered a choice of alternative replies. The purpose of this research was to gain answers to predetermined questions. It was about policy and practice and did not seek to describe attitudes or opinions. For this reason the survey contained only closed questions with fixed responses. A potential disadvantage of this approach was that the responses offered may be too crude or not provide the option that the respondent would have chosen. This could introduce bias by forcing the respondent to choose a response that did not accurately reflect the true answer. An attempt to counter this was made by adding a 'don't know' or 'other, please specify' option for some questions. In addition the questions were piloted among midwives to determine that their understanding of the questions and potential answers was the same as that of the researcher.

Another advantage of closed questions is that the questionnaire is relatively quick to complete. This was seen as a major advantage in surveying so many busy professionals. It was also noted that closed questions would be easier to process and analyse. For the purpose of this research they were deemed appropriate and the best approach.

5.2.3.2 Sequence of questions and layout

Following that the sequence of questions within the questionnaire was considered carefully. This involved identifying groups of questions that related to each other and considering the order of questions to maximise response rate and offer the best chance of complete and accurate data. The overall aim was to develop a questionnaire that flowed in a logical order and made sense to the respondent completing it.

The questionnaire layout followed a funnel type approach. With questions on a broader subject area, such as 'Does your maternity unit currently have a policy of routine antenatal anti-D prophylaxis?' followed by more specific questions about aspects of the policy. It also included 'filter' questions to exclude some respondents from a particular sequence of questions if they were irrelevant to them.

5.2.3.3 Wording

A great deal of consideration was given to the wording of the questions. In particular use of jargon, terminology and technical terms were used only where absolutely necessary and when they were used an explanation was given. Other factors that were considered were: whether words used had alternative meaning or usage; whether questions might be loaded; care not to over-tax respondent's memories; care not to use double-negative questions. Every effort was made to make the questions as short and straight forward as possible.

5.2.3.4 Introductory paragraph

Another measure taken to increase response rate and reduce response bias was the insertion of a paragraph at the start of the questionnaire that gave clear instructions for completing it, for example to tick in the circle, and an explanation of terms used. Additional information at the end of the questionnaire reinforced this and re-stated where to send completed questionnaires.

5.2.3.5 Layout of questionnaire

Oppenhiem (1992) stresses the importance of making the questionnaire and the answering process attractive. The layout, printing and choice of paper should all be carefully considered. All of those factors were taken into consideration prior to printing the questionnaires.

5.2.4 Pilot of questionnaire

A number of midwives were asked informally to comment on the questions to be used in the questionnaire. Changes were made following this and when the researcher was happy with the questionnaire questions and layout it was piloted among a small number of senior midwives. Those midwives were given the questionnaire to complete and following this the researcher went through the completed questionnaires with them clarifying their response and understanding of the questions. Minor changes were required to question wording following this.

In addition the questionnaire contained a field asking the respondent to complete their name and designation and to give an email address or telephone number. This was to allow the researcher to contact them with any queries about responses given or incomplete data.

5.2.5 Administration of questionnaire

The way the questionnaire was administered was regarded as integral to minimising response bias, by ensuring that it reached the intended person, and to maximising response rate.

A number of factors were considered to maximise the chances of the envelope containing the questionnaire to be opened. These included: where possible the questionnaire was posted to a named person, rather than to 'the senior midwife for antenatal care'; the envelope was an office standard envelope, sent via and franked by the Scottish National Blood transfusion Service (SNBTS) mail room. This was intended to increase credibility from the outset through association with another NHS organisation. Oppenheim (1992) calls this 'sponsorship' and describes it as a powerful motivator if the respondent views the organisation involved positively.

The contents of the envelope to be sent were considered carefully in order to maximise the chance of a response. A covering letter was included, offering an opportunity to explain the purpose of the research. Murphy-Black (2000) considers that the survey topic and its relevance to the respondent, as a factor that might positively influence response rate: "the more relevant the topic is to the respondent, the more practical it is to answer, the better the response rate" (Murphy-Black in Cormack, 2000, Pg303). The covering letter also offered another opportunity to reinforce the credibility of the research through association with SNBTS and to establish its purpose, to survey all UK maternity units, reiterating the importance of individual responses within the overall study design. It also offered the reassurance of confidentiality and anonymity in terms of sharing and publication of any data from individual maternity units, deemed vital in reducing non-response bias.

A postage-paid, addressed return envelope was included, again in order to maximise response from a survey that was to be completed by an employee in their workplace. Questionnaires were posted to all 328 UK maternity units in July 2005. The maternity units included private birth units, GP and/or midwife led units and larger maternity units at district general and teaching hospitals. After six weeks non-responders were sent a reminder with a further copy of the questionnaire.

5.3 Data analysis

The questionnaire included a request for a copy of any written patient information about RAADP. A basic analysis was performed of the origin and content of the leaflets returned. Origin was categorised as follows:

1. Commercial: produced by the manufacturers of anti-D immunoglobulin
2. NHS: produced by national NHS bodies such as NICE, NBS and SNBTS
3. Local: produced by local NHS trusts, divisions or maternity units

The content of the leaflet was profiled against twelve key pieces of information identified from the patient information issued with the NICE guidance. These are detailed in the results section, 5.4, (Table 6).

Data were entered into a spread sheet by one researcher, checked and re-checked, and then analysed using the computer software package SPSS v13.

5.4 Findings

A formal break in studies was taken following completion of this piece of work and the length of time between its completion and subsequent write up within the thesis resulted in this chapter being presented as a summary of the research findings. The findings presented here are those that provide a general overview of the implementation of the RAADP guidance.

Replies from 4 of the 328 maternity units surveyed stated that antenatal care was no longer provided at that site. Of the remainder, and following letter and phone calls to non-responders, 91% returned completed questionnaires (294/324).

5.4.1 RAADP

Of all responding maternity units, 220/294 (75%), offered RAADP. In Northern Ireland all 12 maternity units offered RAADP, in England and Wales this figure was 180/243 (74%) and in Scotland 28/39 (72%).

In England and Wales a single dose regimen of RAADP was available as an alternative to the two-dose regime. This was offered by 35/180 (19%) of units offering RAADP.

5.4.2 Paternal testing

Routine paternal blood group testing was offered by 27/220 (12%) of maternity units that offered RAADP though in Northern Ireland this was 11/12.

5.4.3 Education and training to support RAADP

At 9% of units (20/220), implementation of RAADP had not been accompanied by staff education, while for another 9% (19/220) these data were missing. For the 84% of the 181 maternity units who did offer staff education at implementation, it took the form of group training sessions (in the majority of cases with provision of written information). On-going staff education was in place at 100 (45%) of the maternity units who offer RAADP, and this was more likely to be in those with more recent introduction of RAADP.

5.4.4 Written information

Of units offering RAADP, 214/220 (97%) provided written information about it for pregnant women and 147/214 (69%) returned copies of the information that they provide, 30 sending two different leaflets, and 6 sending three. There were 60 distinct leaflets, of which 8 were produced by commercial manufacturers of anti-D Ig, 7 by national NHS bodies and 45 by local NHS trusts or maternity units. The most commonly used leaflets were firstly a commercial one (used by 35 maternity units), and second the NICE leaflet (26 units). Thirty-three leaflets were specific to a single maternity unit.

5.4.4.1 Analysis of leaflets

Analysis of content of the leaflets showed that omission of key information ranged across the recommended key points from 73% to 7% (Table 6, below). Only 3/60 (5%) contained all 12 key pieces of information, while 16 (27%) contained 6 or fewer key points, 3 containing just 3. Considered across the units surveyed and returning leaflets (n=147), the coverage of the leaflets being used was less comprehensive in those units where RAADP had been introduced 'early' (up to year 2002) (Mann Whitney U $p \leq 0.001$; n=31, 105), regardless of whether, in the case of units returning more than one leaflet, the coverage score used in the analysis was that of the worst leaflet, the best leaflet, or of the combination of information across leaflets.

Table 6: Key information used to analyse content of patient information leaflets

Key Information Expected	Number (%) of leaflets that ***omitted*** the information
• *State circumstances in which RAADP is unnecessary*	44/60 (73%)
• *Indicate the actual incidence of Haemolytic Disease of the Newborn (HDN)*	42/60 (70%)
• *Explain that if the father's blood type is also RhD negative then anti-D is not required*	41/60 (68%)
• *Give sources of further information about RAADP: websites or phone numbers*	34/60 (57%)
• *State that RAADP is recommended by NICE /NHS*	34/60 (57%)
• *State the likely risk of viral transmission via anti-D*	13/60 (22%)
• *Explain what haemolytic disease of the newborn is*	11/60 (18%)
• *Explain potentially sensitising events(PSE) and need for anti-D*	10/60 (17%)
• *State that anti-D is a human blood product*	9/60 (15%)
• *Offer further discussion with a midwife or doctor*	8/60 (13%)
• *Explain why the problem occurs*	4/60 (7%)
• *Explain RAADP and how it differs from anti-D prophylaxis following a PSE*	3/60 (5%)

5.5 Discussion

This survey found that there has been widespread implementation of the NICE recommendation for RAADP in the UK. However it also found variation in relation

to specific aspects of policy and the support provided to healthcare professionals whose practice was affected.

5.5.1 Strengths and limitations of this study

A major strength of this survey was the very high response rate (91%), with the findings representing data from almost all of the UK's maternity units. As such the research presents work based on a highly representative sample. The survey also generated a large amount of correspondence which suggests that RAADP was, at that time, a subject of particular interest and relevance to the respondents. This could be regarded as enhancing the quality of the information provided, as those completing the questionnaires were engaged with the subject and motivated to respond.

Weaknesses of the study included lack of control over who completed the questionnaire and potential inaccuracy in the information provided. Measures were taken to reduce the potential impact of the recognised weaknesses, and these were described earlier in this chapter (section 5.2). The principal question was whether or not RAADP was offered at the maternity unit. This question was very straightforward and referred to current practice meaning that responses were likely to be accurate. However some of the questions, in particular those regarding the information and education offered at the time of implementation, may have been more difficult to answer. This might be particularly true of those maternity units where RAADP had been policy for a number of years, and so respondents were referring to events that occurred sometime previously.

The survey questionnaire was intentionally short and simple. This approach was intended to enhance the response rate, however it did mean that the number of questions was limited and those that were asked did not attempt to explore issues in a way that might have added meaning to the results. The intention of this survey was to gain straight forward information about specific aspects of current policy and practice. As well as answering those questions it provides a foundation on which to base further research, although it should be taken into consideration that the research was conducted in 2005 and is a representation of care provided at that time.

5.5.2 Discussion of findings

Clinical guidelines have the potential to improve patient care, reduce regional and local differences in available treatment, and are recognised as a key method for dissemination of best practice. There is however evidence that implementation of National guidance can be patchy (Sheldon et al, 2004). In May 2002, when NICE issued its recommendation for RAADP, it was estimated that only around 12% of maternity units offered the intervention (Chilcott et al, 2004). This survey found that by July 2005 the majority of maternity units (75%) had implemented a policy for RAADP. This represents a substantial move to widespread implementation of the policy within a relatively short period, and comes despite the fact that implementation had clinical, financial, and training and educational implications. Implementing a policy of RAADP requires significant local level multidisciplinary review of policies and practices and allocation of funding and resources to match. This work did not explore what the perceived barriers or enablers for implementation were, but this is an important question for future research regarding on-going delivery of RAADP policy.

The survey identified that not all maternity units were offering RAADP, and also found significant local and regional variations in practice among those maternity units that did offer RAADP. Those variations included how many doses of anti-D Ig are offered and whether or not paternal testing was offered. Variations were also apparent in the education and/or training offered to clinicians to support this change in policy, and in the information provided to pregnant women who are offered RAADP.

The most notable difference in policy among those units that did offer RAADP was whether one or two doses of anti-D Ig were offered. At the time the survey was conducted English and Welsh maternity units had a choice of buying RAADP as two separate injections of 500 IU, given at 28 and then 34weeks gestation, or of a larger single dose of 1250 IU given at 28 weeks gestation. The single dose regimen is simpler in terms of administration and may have an improved compliance rate

compared to the two-dose regimen (MacKenzie et al, 2011), but on reviewing the evidence NICE concluded that it might be slightly less effective in preventing silent sensitisation (NICE, 2002) *{NB: The 2008 NICE review and update changed this advice to state that both regimens are acceptable. This advice did not apply at time this survey was carried out}*. This survey found that in England and Wales around 1 in 5 maternity units offered the single dose regimen, although in Scotland and Northern Ireland anti-D Ig was only offered as a two-dose regimen. Such variation in practice has important implications for those women who move between maternity units during a pregnancy as they might miss a required second dose of anti-D Ig if the area they move to has a policy of single dose RAADP. If clinicians are to offer all RhD negative women the most appropriate care and advice, they need to be aware that practice may vary in other areas. Variations in policy also have important implications for midwifery practice in terms of midwives responsibility and accountability, and these are discussed in more detail below (section 5.5.3).

Another aspect of practice considered by this survey is the issue of paternal blood type testing. If the father of the baby is RhD negative, then the baby must also be RhD negative and so there is no need to give anti-D Ig during pregnancy: either RAADP or following a potentially sensitising event during pregnancy. As such, identifying the father's blood type as RhD negative could prevent unnecessary administration of anti-D Ig. There appears to be general reluctance towards doing this, with reasons often cited anecdotally as potential misidentification by the mother of the father and the extra costs and administration involved in obtaining paternal samples. This is reflected by the fact that just 12% of maternity units routinely offer to test paternal blood type. However, 11 of the 12 maternity units in Northern Ireland (92%) offered routine paternal blood typing. It is interesting to note that transmission of Hepatitis C through contaminated anti-D Ig occurred in Ireland during the 1970's and 80's. The Northern Irish population have close geographical and cultural links with Ireland, and those events may have influenced the decision to offer a test that reduces the number of women who are exposed to anti-D Ig. This may also be influenced by the cognisance of the NHS in Northern Ireland of its organisational

responsibility and accountability, and could also reflect heightened awareness among the general population, pregnant women and healthcare professionals of the potential risks of anti-D Ig as a blood product

The emerging potential for testing fetal blood type through DNA extracted from maternal blood samples may mean that usefulness of paternal testing becomes obsolete. However, the experience of those maternity units that already offer routine paternal testing could provide valuable insight to the practicalities of offering this test and is an area of research that could be explored further.

5.5.3 Implications for midwives

The findings of this survey have important implications for midwives. The survey uncovered a number of situations where midwives' sense of personal and professional responsibility and accountability might be at odds with her obligation as an employee to fulfil her employer's organisational responsibilities. These reflect the evidence based, population focused, nature of the recommendation for RAADP, and the variations in practice that were apparent throughout the UK. As an example, if a midwife was aware of the NICE recommendation for RAADP and the potential benefits that might have for an RhD negative pregnant woman, but the organisation within which she worked did not have a policy to routinely offer it, this might result in perceived conflict with her professional responsibility to "deliver care based on the best available evidence… ensure any advice you give is evidence based." (NMC, 2008, Pg6). The same dilemma might apply to the knowledge that it is possible to test for paternal blood group.

The NICE recommendation is such that should a woman ask for RAADP, then the maternity unit would be obliged to offer it. This was put to the test in 2008 when the Welsh ombudsman upheld a complaint from a pregnant woman whose local health board did not offer RAADP (Public Services Ombudsman for Wales, 2009). However, although an NHS Trust might be obliged to provide RAADP if a woman requests it, there is no legal responsibility to offer it in the first place. This creates a situation where only those women who are well informed and already aware of the

intervention have it as an option. Maternity units are not obliged to provide paternal blood group testing to determine RhD status, and many will only perform the test if parents were willing to pay for it. This further complicates the ethical dilemma in that the test is only available to those parents who request it and who can afford to pay for it.

Another area of midwifery practice for which the findings of this survey are relevant is that of facilitation of informed decision making for women. NICE (2002) reiterated the importance of informed decision making within their guidance document. Informed decision making is important in relation to RAADP, not only because of the balance of risks and benefit, but also because it is an evidence-based recommendation that is based on a population perspective. The recommendation does not take into account individual factors such as whether the woman plans to have a future pregnancy, or whether the baby's father is RhD negative. The literature reviewed in Chapter three suggests that such routine interventions may lead to a culture of compliance rather than fully informed consent. Although there is no research evidence concerning RhD negative pregnant women's perspective on the maternity care they receive, there is a great deal of evidence that "informed choice is unusual in maternity care and compliance is common" (Kirkham, 2004, Pg xvii). The survey gathered information on two factors that influence informed decision-making: provision of written information about RAADP and the education given to key care-givers.

Facilitation of informed decision-making, and appropriate administration of anti-D Ig in line with guidance, will depend upon the clinician's knowledge and understanding of the issues involved. The majority (82%) of maternity units did offer staff education at the time of implementation of RAADP, but only 45% replied that they offered on-going education. On-going education is important in order to maintain staff knowledge and understanding in light of further developments and to address staff turnover. Midwives' have a responsibility to ensure that they "keep their knowledge and skills up to date throughout their working life" (NMC, 2008, Pg6). Equally employers have responsibility to support staff and do all they can to ensure

that the midwives they employ are fit to practice (NMC, 2008). Within the limitations of this survey it is impossible to make any judgements about the content or quality of the education offered, but this is another important question for future research.

With the lengthening list of issues to discuss at antenatal appointments and the pressure on time available for appointments, clinicians are increasingly dependent on written patient information. This may be particularly true of an intervention such as RAADP where the risks and benefits are complex and vary depending on an individual's circumstances. The survey found that the overwhelming majority of maternity units provide written information, however the content of the leaflets varied considerably and almost all omitted at least some of the information that is considered of key importance. The information that was most commonly omitted was that which might have led a woman to decide that, based on her own individual circumstances, the risks of RAADP outweighed the benefits (Table 6).

On issuing its recommendation for RAADP, NICE (2002) stated that high quality information, validated and produced at National (UK) level, must be made available to RhD negative women. They produced their own patient information leaflet, but at the time of the survey the NICE leaflet was used by just 15% of those units that returned leaflets. Locally produced leaflets were being used by nearly a third (32%). This raises the question: why did so many maternity units opt to produce their own leaflets? A time consuming and expensive option, particularly when a leaflet that was produced by the NICE expert group on RAADP was widely available (the leaflet can be downloaded from the NICE website). Analysis of the content of the leaflets found that that key information was omitted in the non-NICE leaflets used by 73% of responding maternity units. The fact that the locally produced leaflets were less likely to contain information that might lead women to decide to decline RAADP, raises the difficult question of whether the maternity units were inclined to produce leaflets that they felt supported their policy for RAADP. The literature reviewed in Chapter three suggests that some healthcare professionals resist providing detailed written information for women through fear of creating anxiety. This could be a

reason for omission of some of the key information when leaflets were produced by the maternity units. These questions are beyond the scope of this research, but again are important and relevant for midwives who rely on written information as tool for facilitation of informed decision making.

The issue of quality around locally produced leaflets does not just concern content, it is also raises the question of whether expertise in written communication for patients was available to those producing 'local' leaflets. Women's ability to understand and process the information contained within the leaflets, in a manner that enables an informed decision about RAADP, is as important as the content. This survey did not address this question, and similarly did not explore whether the midwives engaged further with the women to discuss RAADP in greater detail than was apparent from the leaflets. The varied content and quality of the leaflets highlights further the disparity in care provided by different maternity units and suggests a need for a co-ordinated national approach for the production and dissemination of high quality information for pregnant women.

Interestingly, those implementing RAADP *after* NICE issued their guidance used more comprehensive leaflets. On-going staff education was also more likely in maternity units that had implemented RAADP more recently. This suggests that the NICE guidance has had a positive impact on the information available to patients, both written and through care-givers. However this also raises concern as to whether those maternity units where RAADP was introduced prior to 2003 have reviewed and updated their information and staff training in light of the new guidance.

5.5.4 Implications for further research

The survey findings highlight a number of questions that are important for future research. They include:

- What are the perceived barriers and/or enablers to implementation of a policy to offer RAADP?
- What is the present state of implementation?

- What is the experience of women, their partners and midwives at those maternity units where paternal blood type testing is routinely offered?
- Are maternity units still producing their own leaflets regarding anti-D Ig?

And if so…

- What drives the choice to produce written information locally when there is nationally produced and validated information readily and freely available?
- How have changes to maternity service provision since 2004 impacted on delivery of a policy of RAADP?

This survey also raised a number of questions about midwifery practice that the researcher will explore further during this thesis. In particular it was considered important to explore what education and/or training midwives received in relation to RAADP and anti-D Ig in general. Although the survey found that most units did offer education it was not clear what form this took, nor what impact it had on midwives' knowledge, understanding and practice. Additionally the survey showed a wide variation in the type of written information provided for pregnant women with an RhD negative blood type. The literature review in Chapter three suggests that midwives are increasingly dependent on written information to support informed decision making. The researcher was keen to explore further what part written information played in the process of informed decision making around this issue. This was considered particularly relevant given the emphasis placed on decision making around RAADP by organisations such as NICE, the Royal College of Obstetricians and Gynaecologists and the Royal College of Midwives. At the heart of both of these issues are important questions about midwives' personal and professional responsibility and accountability. Midwives' knowledge and understanding of the issues is key to their ability to provide appropriate care for women, and this clearly extends to supporting a woman to make a decision about RAADP based on her individual circumstances.

This research demonstrated that RAADP has become a routine aspect of maternity care throughout the UK, and in doing so highlighted the increased involvement that midwives have in the administration of anti-D Ig. The research presented in the following Chapters, six and seven, is designed within the context of the findings presented here and the questions those findings raise.

Chapter 6: Anti-D Ig: analysis of midwifery errors reported to SHOT

Anti-D immunoglobulin (Ig) is offered to all pregnant women with an RhD negative blood type, around 1 in 6 UK maternity patients. Failure to administer anti-D Ig in line with guidance has potentially serious consequences and all adverse events relating to anti-D Ig should be reported for inclusion in the Serious Hazards of Transfusion (SHOT) annual report. This information is useful in identifying trends and, alongside observations from a small number of 'stand out' error reports, allows SHOT to make recommendations for practice based on data observed over a number of years. The extent to which other potential contributory factors are explored is very limited. Although midwives have a key role in the administration of anti-D Ig, there is not a midwife involved in the analysis of the SHOT data and the data are not considered from a clinical midwifery perspective.

This research builds on the SHOT approach to analysis, considering the data from a midwifery perspective and seeking to identify clinically relevant issues. The aim of this part of the thesis is to describe the type of anti-D Ig errors made by midwives and the factors that lead the midwives to make them. It was hoped that this would allow better understanding of why errors happen and what can be done to prevent them from happening in the future. It also gathered data to inform the next stage of this research: Anti-D Ig: focus group research to gain midwives' perspective.

6.1 Background

Some evidence relevant to this chapter was presented in Chapters two and three, however it is useful to discuss here some of the policies, procedures and ways of working that are particularly relevant to this chapter.

6.1.1 Anti-D Ig

Administration of anti-D Ig sits within a complex framework where laboratory, medical and midwifery staff, and the woman herself must interact effectively in order to ensure that the correct woman receives the correct dose of anti-D Ig according to

her individual clinical circumstances. Midwives in particular have a key role in administration of anti-D Ig, this is detailed in section 2.4, with the policy for anti-D Ig administration and associated blood testing in Table 1, section 2.2.

Anti-D Ig is a human blood product, and as such, is strictly controlled. All anti-D Ig should be fully traceable from recipient back to donor (via a batch number). In the UK, prior to the introduction of routine antenatal anti-D prophylaxis (RAADP), all anti-D Ig was held by the hospital blood bank or transfusion laboratory and issued to the clinical area as required and on a named patient basis. That is the correct dose of anti-D Ig was sent directly from the laboratory to the area requesting it, with documentation linking that vial or vials, to the named patient for whom it had been requested. The introduction of RAADP, offered to all RhD negative women during pregnancy, meant that some maternity units found this arrangement impractical and began holding stock of anti-D Ig in clinical areas. This allows anti-D Ig to be used as required by staff without directly involving the blood bank or transfusion laboratory. This arrangement is particularly useful for staff holding clinics out-with the hospital setting, for example at GP surgeries. Although holding remote stock makes the anti-D Ig more accessible it also removes the extra control that the laboratory have over its issue and it has been argued that it may increase the likelihood of errors. It is not known how many maternity units have an arrangement to hold ‘remote stock’ of anti-D Ig, but not all do. Anti-D Ig should be stored in a validated medicine or blood fridge.

6.1.2 Incident reporting

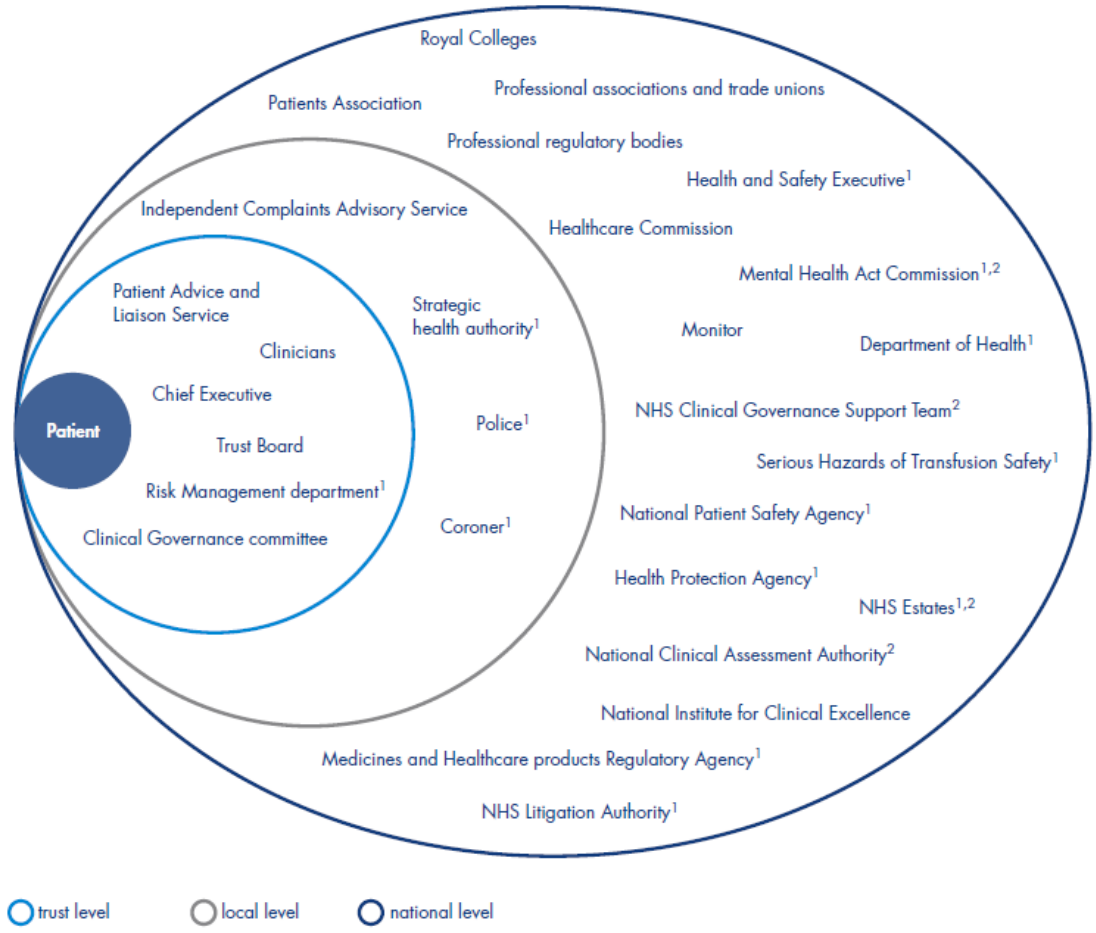
The first step in learning from mistakes, in order to reduce the risk of recurrence, is to collect information about any adverse incidents that occur. This enables errors that impact patient care to be monitored, managed and reported via risk management process and then linked to professional and organisational learning through NHS Boards and clinical governance structure. Reporting systems are seen as crucial to

> “Providing a core of sound, representative information on which to base analysis and recommendations”
>
> DOH (2000, Pg ix).

Local reporting systems should provide the bedrock for onward reporting to regional or national systems.

The report ‘Organisation with memory’ (DOH, 2000) found that all NHS trusts, in England and Wales, had established effective reporting systems at local level. Clinical governance and risk management standards depend on systematic identification and treatment of risk, with incidents recorded and reviewed as part of a system of risk management. Clinical errors and incidents should be analysed and used as basis for improving quality of treatments, services and premises. Systems can be paper based or electronic/web-based e.g. DATIX or Safecode. The National Audit Office report (National Audit Office, 2005) found that incidents were often analysed at local level with relevant information passed onto one or more of around 30 organisations, including the Serious Hazards of Transfusion haemovigilance scheme (SHOT), Figure 4, below.

Figure 4: Incident reporting from trust to national level



Source: National Audit Office (2005, Pg3). Copyright National Audit Office

6.1.3 Anti-D Ig incident reporting

Any errors involving blood components, including anti-D Ig, must be reported to SHOT. Formal systems for recognising and reporting errors will differ between geographical areas and maternity units, however anti-D Ig errors are commonly recognised by the laboratory staff who conduct blood testing and issue anti-D Ig, the clinicians delivering care, either at point of error or afterwards, or occasionally by the woman herself. Initially these errors should be submitted via the local formal incident reporting system in the laboratory or clinical area, such as DATIX. Any incidents that meet criteria for reporting to SHOT will then usually be identified by hospital transfusion practitioners (criteria for reporting anti-D Ig errors are described

in Table 7). Some may also be reported to SHOT directly by the clinicians, medical and midwifery or laboratory staff involved. A standard reporting online form, available through the SHOT website to registered users, is used to collate the reports.

In the past reporting to SHOT was voluntary but in recent years a number of quality, inspection and accreditation organisations and government bodies within the UK have made reporting to SHOT a requirement. These include: The National Patient Safety Agency (England and Wales), Department of Health (England), Welsh Assembly Government, Department of Health and Social Service and Public Safety Northern Ireland and NHS Quality Improvement Scotland (QIS, now HIS). This means that all errors and incidents involving anti-D Ig, in the UK, should be captured by the SHOT database. The SHOT scheme is confidential.

SHOT publish an annual report, within which the errors are categorised according to whether the primary error occurred in the laboratory or the clinical area and according to type of error (Table 7). In the 2008 SHOT annual report the definition of an adverse event relating to anti-D immunoglobulin is given as:

> *'An event relating to the prescription, administration or omission of anti-D Ig that has the potential to cause harm to the mother or foetus immediately or in the future.'*
>
> (Taylor et al, 2009, Pg82)

SHOT collate errors in four broad categories. The error categories and their potential clinical consequences are described in Table 7 (below).

Table 7: Anti-D Ig error categories used by SHOT

SHOT error category	Error	Potential Consequence
Omission or late administration of anti-D Ig	• Anti-D Ig is omitted completely, or administered more than 72hours following potentially sensitising event (PSE), delivery of an RhD positive baby or as RAADP.	Failure to administer anti-D Ig within 72hours of a PSE or delivery of an RhD positive baby puts the woman at risk of sensitisation with anti-D antibodies. Her future pregnancies may be at risk of Haemolytic Disease of the Fetus or Newborn (HDFN).
Inappropriate Administration of anti-D Ig	• Anti-D Ig is administered to an RhD negative woman known to have anti-D antibodies or known to have an RhD positive baby. • Anti-D Ig administered to an RhD positive woman. • Anti-D Ig administered to the wrong person.	If anti-D Ig is administered to an RhD negative pregnant woman unnecessarily, there are no known physiological consequences, however she will have been unnecessarily exposed to a human blood product. Anti-D Ig is considered exceptionally safe, but transmission of known or as yet unknown blood borne viruses cannot be completely ruled out. If anti-D Ig is administered to an RhD positive woman she is exposed to the same risk associated with a blood product. In addition there is a risk that the anti-D Ig will cause some haemolysis of her RhD positive red blood cells, although this is highly unlikely to cause significant physiological problem.
Wrong dose of anti-D Ig given	• Inappropriate dose of anti-D Ig administered: according to gestation and/or Kleihauer test result.	Failure to administer the correct dose of anti-D Ig puts the woman at risk of sensitisation, her future pregnancies may be at risk of HDFN.
Administration of expired or out of temperature control anti-D	• Anti-D Ig should be should be administered on or before the expiry date stated in the vial.	Failure to do this may result in reduced effectiveness of the product and subsequently place the woman at risk of sensitisation with anti-D antibodies. Her future pregnancies may be at risk of HDFN.

The report also gives some specific examples of errors that have occurred and provides recommendations for practice based on errors within that reporting year and on cumulative data and trends observed over a number of years.

6.2 Method

The researcher was given access to all 136 SHOT incident reports that had been submitted for inclusion to the 2008 annual SHOT report (Taylor et al, 2009). These were provided in their original form, on an Excel spread sheet. Data collection is an extremely important aspect of the overall study design, however in this case the data had already been collected and so the researcher had no control over this. The researcher had, instead, to determine whether the data collection had been robust and to consider any aspects of the collection process that might influence the data's suitability for use within this study design.

As already discussed, there is a strong culture of using incident reports throughout the National Health Service (NHS). Reporting is now mandatory when an adverse event occurs, and onward reporting to SHOT is also mandatory. The data available for analysis contained all recognised adverse events relating to anti-D Ig that occurred within UK NHS organisations, and were reported to SHOT, during a 12 month period in 2007/2008. Although Taylor et al (2009) acknowledge that SHOT does not receive all possible error reports, this data set represented the most complete information available concerning errors relating to anti-D Ig in the UK

A major factor when considering use of the SHOT error reports was that there was no information about who conducted the initial report and investigation, or how that was undertaken. The reports came from across the UK and so would have been completed by a number of different people. Varied approaches to investigation and information gathering will have been used, resulting in inevitable, but unknown, biases. The reporting system was an online questionnaire and the 2008 SHOT annual report acknowledged that the system in use when this data were collected was not

user friendly. Completing the online questionnaire was a lengthy process often involving scrolling through multiple pages to find questions relevant to a particular type of report (Taylor et al, 2009). This too may have impacted on the content and quality of the data contained within each form.

The information contained within the SHOT incident reports contained fixed responses to closed questions as well as free text narrative. The individual incident reports describe details of the incident, the findings of any investigation held and an outline of any action taken as a result. The investigation undertaken is most often based on root cause analysis. Root cause analysis (RCA) is now the main way that medicine investigates mistakes and tries to prevent future mistakes (Wu, 2008). It has its origins in manufacturing industries and was first used in a healthcare setting by the Veterans Affairs Hospitals in the United States (Heget et al, 2002). It is used across a number of countries including the UK, where it has been adopted by the National Patient safety Agency (National Patient Safety Agency, 2011). RCA is a problem solving method that provides a structure to the retrospective analysis of errors. The process can take different formats, but usually a clinical team who were not involved in the incident investigates what happened, with the aim of identifying the causes of the incident and developing recommendations for change (Iedema et al, 2008). It should be a systems based approach, rather than focussing blame on an individual. Wu (2008) describes the RCA process as designed to answer three questions: what happened, why did it happen, and what can be done to prevent it happening again?

Flanagan (1954) suggests that the primary aim of scientific techniques are to ensure objectivity of the observations being made and reported, and that this can only happen if all observers are following the same set of rules. It is important to acknowledge that it was beyond the researcher's control to determine whether the data collection and reporting was robust. In fact, it was likely that the means of collecting and collating the information made it susceptible to significant bias. However, the data available for analysis represented a unique opportunity to conduct

research using the most complete information concerning clinical errors relating to anti-D Ig which was available in the UK.

6.3 Data analysis

The spread sheet contained 136 incident reports but on further reading one of the reports was a duplicate, leaving 135 complete reports. For this research only incidents where a midwife was involved at some point in the process were included.

Some of the errors included in this research as midwifery errors had originally been categorised as 'laboratory' errors in the analysis completed by the SHOT team. An example of this is where the laboratory issued anti-D Ig in error to a woman with an RhD positive blood type, but the midwife administered it anyway: although the laboratory made the initial error, the midwife made her own error by failing to complete checks that would have picked up the mistake and prevented administration of the anti-D Ig. There were also eight cases where SHOT had categorised the error as 'clinical' but a midwife was not involved. These included errors occurring in accident and emergency departments and gynaecology wards (areas where nurses rather than midwives practise) and other reports where it was clear that only medical staff were involved. Those eight reports were excluded.

In a small number of the reports it was not clear precisely who had been involved in the error and it could have been a member of medical or nursing staff rather than a midwife. When the information contained in the report was sufficient to determine the clinical context and that the error could possibly have been made by a midwife, it was decided to include those cases and assume for the purpose of this project that a midwife had been involved.

The reports were read and re-read and any reports where a midwife was involved in the error were identified. There were 105 such reports but 3 contained insufficient information to allow any meaningful analysis, leaving 102 reports suitable for analysis. The process for deciding to include or exclude reports is detailed in Table 8, below.

Table 8: Exclusion process for SHOT error reports

		Number of Reports
Total: all available reports (one duplicate report excluded)		135
Exclusion Criteria	Solely Laboratory Errors	16
	Other Reasons/Staff groups out with midwifery influence	8
	Not enough information available to determine whether a midwife was involved	6
	Midwife involved but not enough information to allow analysis	3
Total Excluded Cases		33
Total Included Cases (Midwife possibly involved at some stage)		102

The errors were allocated ‘case numbers’, with each incident having a unique number from 1 through to 102.

The data analysis was multi-faceted, with three aspects:

1. Simple classification of the incidents
2. Detailed description of the incidents
3. Identification of key aspects of the incidents

These methods were interconnected and complimentary, each describing different aspects of the incidents. The methods were focussed, but also evolved and adapted as the analysis progressed, taking into account findings as they were emerged. They are described in further detail below.

6.3.1 Simple classification of incidents

The SHOT reporting scheme categorises the reports they receive into type of anti-D Ig incident and according to staff group deemed responsible for the error. In the first instance the data were analysed using an approach similar to that used by the SHOT reports: identifying categories and quantifying the error reports according to the numbers and types of incident. Although the approach mirrored the SHOT approach to data categorisation, the design differed in that it only included those errors that involved a midwife.

6.3.2 Detailed description of the incidents

The aim of this aspect of the analysis was to look at each incident in more depth in order to describe them in more detail and to identify common themes among the errors. The methodology employed for this part of the research used an interpretative approach based on critical incident technique (CIT). This allowed identification of similarities and/or common elements leading to category formation.

CIT is a qualitative research approach that can be used to analyse clinical incidents and errors, with Wright et al (1991, Pg 676) defining a critical incident as “an occurrence that could have led (if not discovered and corrected in time), or did lead, to an undesirable outcome’. It has its roots in the military, where psychologists used the method to better understand pilot behaviour during the Second World War, and was further developed by the psychologist Flanagan during the 1950’s. Flanagan (1954) determined that the method was extremely flexible and likely to have many types of applications, and it has since been successfully applied in the healthcare setting, particularly in specialities such as anaesthesia and critical care (Donchin et al, 2003). CIT is not a rigid research methodology, rather it is a flexible set of principles that can be modified and adapted for specific situations (Flanagan, 1954).

This flexibility is particularly useful for analysing and interpreting data collected from the 'real' situation of clinical practice. Understanding ineffective clinical care is crucial to promoting effective clinical care: by looking systematically for areas of weakness that may have contributed to an undesired outcome, it is possible to identify errors that are both clinically significant and prevalent. Many health care organisations now see the value of incident reporting as a multidisciplinary approach to reorganising care in a way that will make it safer and more effective. It offers a robust and systematic approach to clinical problems and Iedema (1991) describes the intent of CIT as being to shape work practices rather than making judgements about the actions of specific individuals. It allows a better understanding of how the systems and routines of practice contributed to what went wrong and to what extent they could be redesigned.

As with any research methodology, CIT has advantages and disadvantages. One disadvantage of CIT is that it relies on the recall and report writing skills of the respondents, and may also be limited by the format in which people are asked to report: for example the questions they are asked on the reporting form, or by the amount of time that has elapsed between the event occurring and the report being compiled. The report may also suffer from personal bias from the person doing the reporting, although having a standard incident report form can help to ease this bias.

For this particular research the main advantage of CIT is that the reporting of incidents involves descriptions of actual events, rather than of events as they should be. This is particularly helpful when applying the findings to effect change in practice, or to inform educational content for clinicians. The aim of this aspect of the data analysis was to provide a detailed description of the incidents. An approach based on CIT methodology was used to identify major categories which were then related to common themes, within which smaller categories and then sub-categories are identified. These were all related back to the broader categorisation that had been conducted initially. The number of each category and subcategory were then recorded. Cormack (2000, Pg332) describes this as an inductive classification of incidents with the "classification system constructed as the data are being analysed,

rather than before". Flanagan (1954) also describes the process of creating the categories as inductive and relatively subjective, but considers that once the classification system is in place, objectivity can be achieved in placing incidents in defined categories. This was achieved by reading and re-reading the incidents, identifying emergent categories and themes and then re-reading the reports further to confirm categories. Cormack (2000) suggests creating categories until all incidents have been classified, leading to a two or three tier system that starts with a very general description and progresses to become increasingly more specific. By following this process it was possible to map common occurrences and general themes among the reports.

In addition the data were examined in order to discover the absolute cause: the definitive, final error made by a midwife that resulted in the incident. When all other factors and influences were disregarded it was possible to identify just four 'proximal errors'.

6.3.3 Identification of key aspects of the incidents

The initial categorisation and the detailed description of the incidents were used to shed light on the types and frequency of anti-D Ig incidents that involve midwives and to describe common details of those incidents. It describes the facts of the errors: that is what had actually happened, the process and the mistakes made. Another aim of this research was to try to describe factors that influence the errors, in particular the key aspects of the error that might be identified in advance and changed to prevent recurrence. In order to do this an approach to analysis, drawing from Reason's model of understanding adverse events (Reason, 2000), was developed specifically for this research. The approach focused on uncovering three elements of the errors named 'proximal errors' 'trigger events' and 'fallible practices'. They were regarded as interactive, contributing in varying degrees to the likelihood of the error occurring and are described in detail below.

a) Proximal errors

The detailed analysis identified that in all of the incident reports the final error lay with the midwife acting or failing to act. This was termed a 'proximal error'. The proximal error was often the final opportunity to prevent an adverse incident, without which it would not have happened. The proximal errors reflect the work of Reason (2000) in which he describes a person approach that focuses on the unsafe act and views it as resulting from human issues such as forgetfulness, poor motivation, carelessness or recklessness. Reason (2000) considers that these 'active failures' can be hard to predict, the person approach regards them as the cause of the error and looks no further.

In almost all of the incidents other factors had direct and/or indirect influence on the proximal error. Reason (2000) also describes a system approach to error, here the important question shifts from who made the mistake to how and why barriers and defences failed. The proximal errors formed the foundation of the analysis, with the researcher working back through each incident to identify the 'trigger events' and 'fallible practices' that impacted the errors.

b) Trigger events

Trigger event is the term coined to describe the event(s) or situation that directly influenced the error. For example, in the case of administration of date expired anti-D Ig, the trigger event might be that a vial of date expired anti-D Ig was available for use in the fridge in the clinical area. Trigger events are similar to Reason's (2003) error traps and identification and elimination of trigger events or situations is key to preventing an adverse event. The trigger events are errors in themselves but would not necessarily always lead to an adverse event. It is likely that in most cases the trigger event would be recognised and rectified before an adverse event occurred, but if the midwife fails to recognise the trigger event because she makes her own proximal error, then an adverse event will occur. The error reports were examined, in order to identify trigger events.

c) Fallible practices

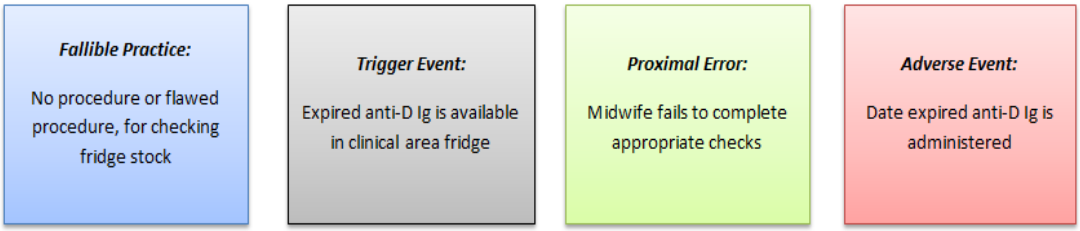
Analysis also identified policies, procedures, practices or documents within the clinical area that were flawed in such a way that they permitted, or even encouraged, a trigger event to happen. These were termed ‘fallible practices’. Fallible practices essentially allow the trigger events, and ultimately the error, to happen.

Following on the example of administration of expired anti-D Ig, the fallible practice would be an inadequate procedure for checking anti-D Ig stock held in the clinical fridge. This leads to the trigger event, in this case that date expired anti-D Ig is available in the clinical area fridge. In turn if the midwife makes her proximal error and does not check expiry date an adverse incident, the woman receiving date expired anti-D Ig, occurs. Had an adequate procedure for checking stock been in place any anti-D Ig close to expiry date would have been returned to the laboratory and either disposed of or issued directly by the laboratory to be given within its expiry date. In this example, if the fallible practice had been addressed the trigger event or situation would not have existed and so even if the midwife fails to complete her checks, it would not lead to an adverse incident.

The relationship between fallible practices, trigger events and proximal errors varies depending on the incident. In some cases there is a very straightforward link with fallible practices having a direct influence on the proximal error. However the relationship between the factors can also be more complex.

All of the incident reports were analysed in the context of this framework. With the proximal errors as a starting point it was possible to re-examine the incident reports and identify trigger events and fallible practices. These were considered in the context of the individual incident report, and in addition the most common frameworks, the interaction of fallible practices, trigger events and proximal errors, were also identified. Figure 5 illustrates the use of the model to identify the key aspects of an incident where date expired anti-D Ig is administered.

Figure 5: Key aspects of incident: administration of date expired anti-D Ig



6.4 Findings

6.4.1 Simple classification of the incidents and root cause analysis to determine proximal errors

Initially the 102 error reports were categorised using the four main SHOT categories: Inappropriate administration 47 (46%); Late/Omitted anti-D Ig 44 (43%); Wrong dose of anti-D Ig given 8 (8%) and expired anti-D Ig given 3 (3%).

During the analysis four proximal errors were identified:

- Failure to complete appropriate checks, 53 (52%)
- Failure to follow up care, 34 (33%)
- Misinterpretation of results, 7 (7%)
- Failure to follow guidelines, 7 (7%)

In one additional error report the proximal error could have been either failure to complete appropriate checks or failure to follow guidelines, this was not clear from the information provided within the report.

Although the proximal errors were identified during the detailed description part of the analysis, they are reported here to allow the findings to be related to classification of incidents.

i) Inappropriate administration of anti-D Ig

The findings are summarised in Table 9, below.

Table 9: Categorisation of error reports: inappropriate administration of anti-D Ig

Inappropriate administration of anti-D Ig N=47	
To an RhD positive woman	34 (72%)
To a woman with immune anti-D antibodies	8 (17%)
To a woman with an RhD negative baby	4 (9%)
To an RhD negative woman who was not the intended recipient	1 (0.5%)

In this category there were just two proximal errors: failure to complete appropriate checks, either confirming the woman's identification or confirming test results formally, 42 (89%); and misinterpretation of results, either misunderstanding the meaning of results or straight forward misreading or mishearing of a report 5 (11%).

ii) Late/omitted anti-D Ig

The 44 late and omitted anti-D Ig errors were categorised according to type of incident: anti-D Ig given late, 34 (77%), or omitted completely, 10 (23%).

In the majority of cases, 34/44 (77%), failure of the midwife to follow up on care was the proximal error. This was either failure to follow up results of samples taken, or failure to administer anti-D Ig that was required. Other proximal errors were: failure to follow guidelines, 6; failure to complete appropriate checks, 2; misinterpretation of results, 2.

iii) Wrong dose of anti-D Ig given

In eight of the reports a wrong dose of anti-D Ig was given. In seven cases the wrong dose was given unintentionally. There was one case where the wrong dose of anti-D Ig was given deliberately due to misunderstanding of guidelines for administration

following a potentially sensitising event in close proximity to the 28 week routine antenatal anti-D Ig injection.

The proximal error was failure to complete appropriate checks in six cases, failure to follow policy/guidelines in one and in the other one case it could have been either of those root errors but it was not clear from the information contained within the report.

iv) Date expired Anti-D Ig given

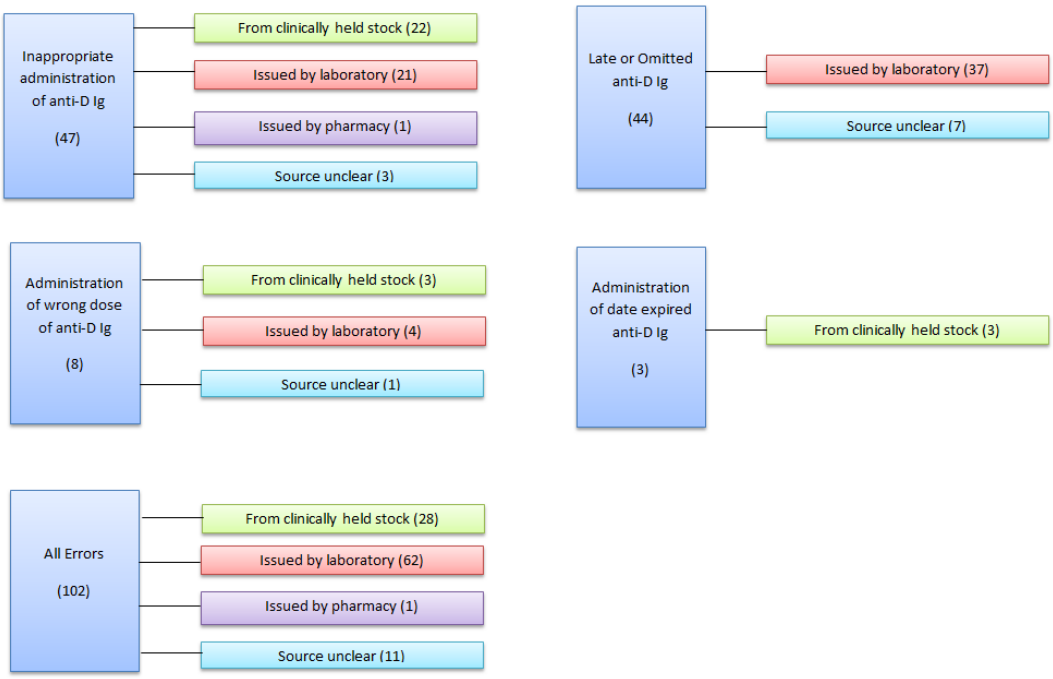
There were three cases in this category. All three reports were very similar and described midwives taking anti-D Ig from stock held in the clinical area and failing to check the expiry date prior to administration.

6.4.1.1 Source of anti-D Ig

The error reports were reviewed to determine the source of anti-D Ig involved in the error. That is whether it was anti-D Ig that had been issued by the laboratory for a named patient, or anti-D Ig taken from stock held in the clinical area.

Of the 102 reports, in 61 (60%) the anti-D Ig had been issued by the laboratory, in 28 (27%) it came from clinical stock and in 12 (12%) it was unclear from the report what the origin of anti-D Ig had been. In one other case it had been issued by a pharmacy. Figure 6 shows source of anti-D Ig according to the type of error made.

Figure 6: Source of anti-D Ig according to error classification



6.4.1.2 How the error was detected

The SHOT error reports contained a field: 'How was error detected?' describing the way the error has been discovered. There were four categories: laboratory staff noted an error; clinical staff noted the error; the patient noted the error and other. The means of detection of error were categorised according to type of incident. The findings are presented in Table 10.

Table 10: Means of detecting anti-D Ig error

	Laboratory staff noted error	Clinical staff noted error	Patient noted error	Other/ Unavailable	Total
Inappropriate Administration	22	15	0	10	47
Late/Omitted anti-D Ig	20	22	2	0	44
Wrong dose of anti-D Ig given	4	2	1	1	8
Expired anti-D Ig given	2	1	0	0	3
Total	48 (47%)	40 (39%)	3 (3%)	11(11%)	102

6.4.1.3 Routine antenatal anti-D prophylaxis (RAADP)

The 102 error reports were analysed to determine how many errors were related to administration of RAADP. In 74 (73%) of error reports, the incident definitely did not involve RAADP. In 13 (12%) the error definitely did involve RAADP. In the remaining 15 (15%) cases it was possible, but not explicit, that the error could have involved RAADP.

6.4.2 Detailed description of the errors

The data analysis identified common situations, processes and/or actions among the incident reports. There were ten sub-categories of errors which are described below. In addition charts are used to illustrate pathways of errors according to classification of type of error: figures 7, 8, 9 and 10 (below).

a) Misinterpretation of results

All of these cases involved a woman who was RhD positive mistakenly receiving anti-D Ig. They resulted from misreading of written reports, telephone report of results being misheard or wrongly transcribed and blood sample results accessed electronically and wrongly interpreted.

b) Results not available

In some incidents the midwife did not know the woman's blood group for sure but gave anti-D Ig anyway, the women were then subsequently revealed to be RhD positive. In other cases anti-D Ig was given to postnatal mothers before the baby's blood type result was available, and the babies were in fact RhD negative.

c) Transcription error/wrong documentation in notes.

In all but one of these errors the woman's blood type had been incorrectly documented as RhD negative in her notes, either hand written or using a stamp or sticker. In the other case a woman was mistakenly booked into an RAADP clinic and received anti-D Ig without anyone checking her blood group.

d) Failure to complete identification checks.

There were a number of cases where a woman received anti-D Ig that was not intended for her and where it was clear that identification checks were not completed at point of administration.

e) Primary error by another health care professional.

The errors in this category included instances where RhD positive women, mothers of RhD negative babies, and women who were already sensitised received anti-D Ig.

In the majority the laboratory mistakenly issued anti-D Ig and the midwife gave it without undertaking further checks. Other cases saw medical staff incorrectly prescribe anti-D Ig which was then given by a midwife who did not confirm the woman's blood group, two of those three cases involved General Practitioners. There were also cases where the laboratory erroneously issued the wrong dose of anti-D Ig and midwives administered it without noticing the error.

f) Anti-D Ig not collected from laboratory or left unnoticed in clinical area fridge

This was a very common error and in most reports there was little further information about why the anti-D Ig was not collected.

g) Blood sample or request form error

There error reports where a problem with a blood sample or request form meant that the laboratory did not complete the test and consequently the results were not reported and anti-D Ig was not issued. These included cases where delivery samples were not sent for testing, the request form was incorrectly completed and laboratory staff did not realise samples were from a pregnant RhD negative woman who might require anti-D Ig, and in one case a sample took 12 days to reach the laboratory.

h) Misinterpretation of instructions/guidelines

The cases in this category involved potentially sensitising events during pregnancy, postnatal prophylaxis and the other two the circumstances were not clear from the report.

i) Unneeded second injection of anti-D Ig given

In these cases the midwife had been unaware that anti-D Ig had been given and requested further anti-D Ig which the laboratory issued.

j) The wrong dose of anti-D Ig selected from stock

In all of these reports the midwives selected the wrong dose of anti-D Ig from stock held in the clinical area.

6.4.3 Illustration of pathways of errors

The following figures are used to illustrate the pathways of error, according to classification type.

Figure 7: Pathway of errors, inappropriate administration

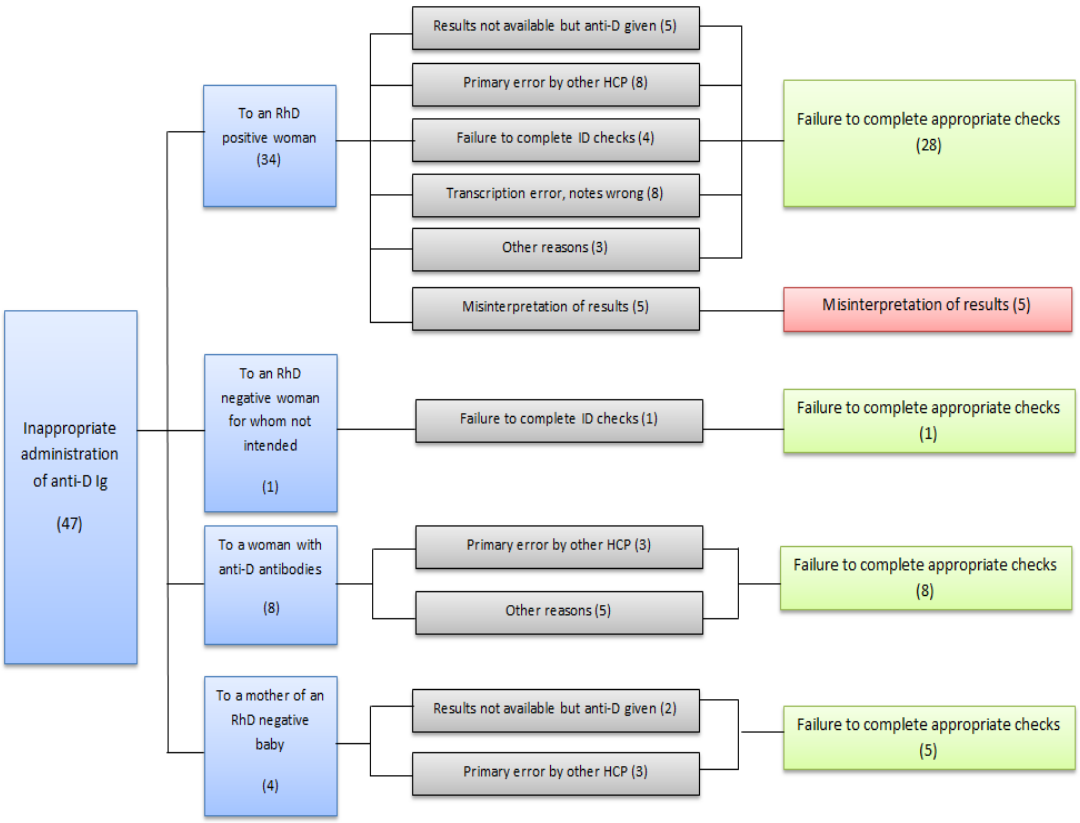


Figure 8: Pathway of errors, late or omitted anti-D Ig

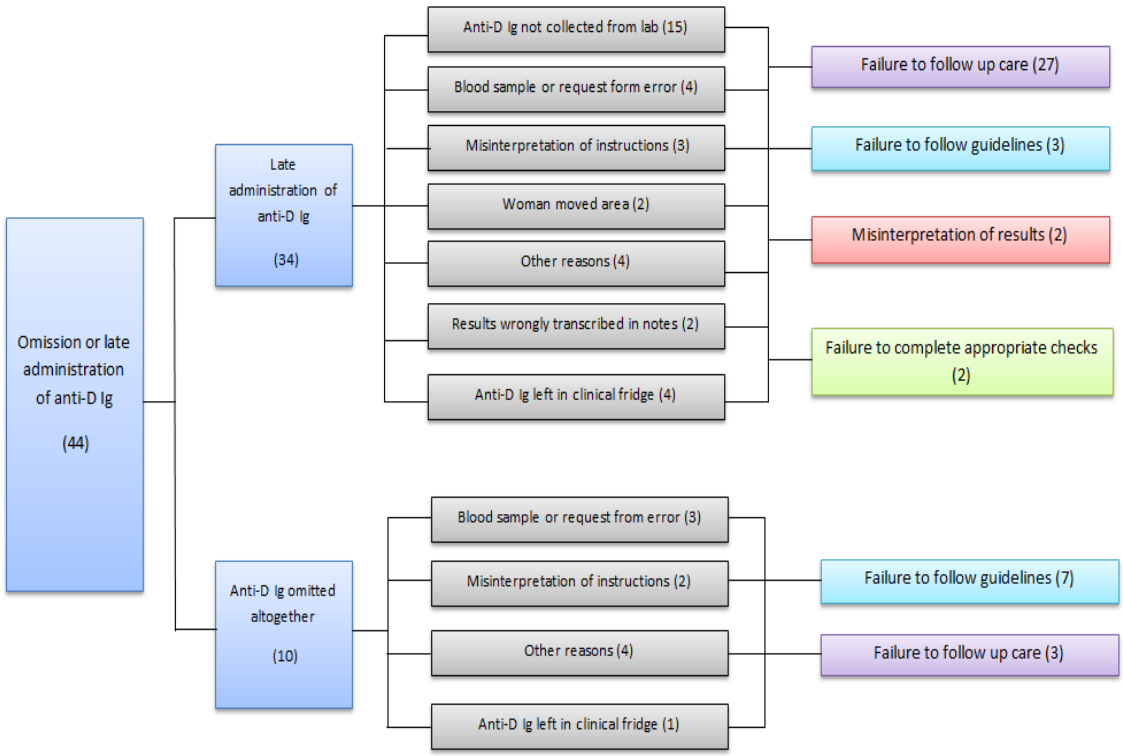


Figure 9: Pathway of errors, wrong dose of anti-D Ig administered

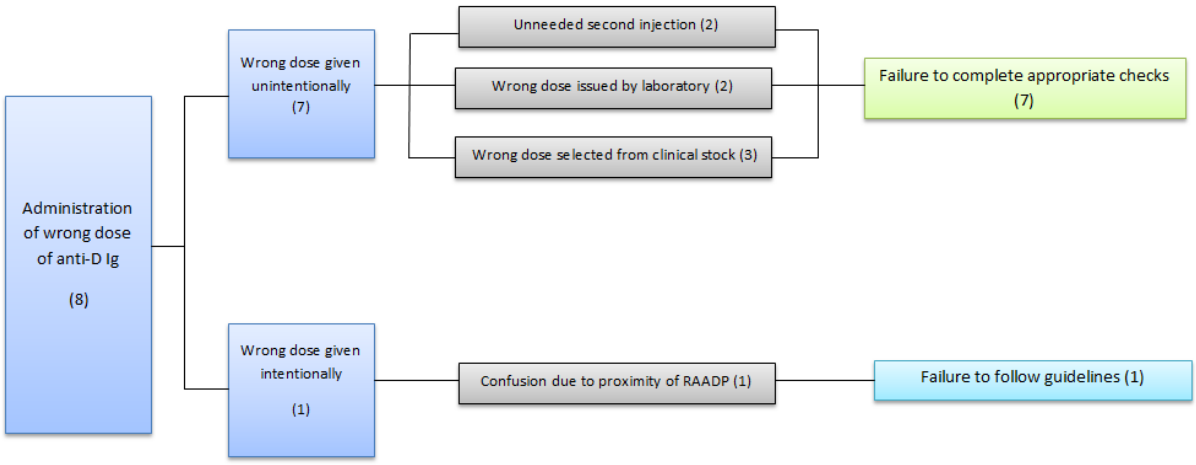
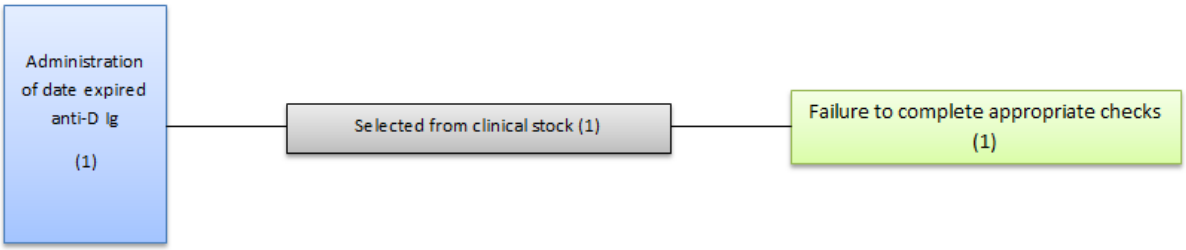


Figure 10: Pathway of errors, date expired anti-D Ig administered



6.4.3.1 General themes emerging from the data

It was also possible to identify common themes among many of the error reports.

i) Presence of immune anti-D antibodies

It is estimated that between 1.2% and 1.8% of RhD negative women in the UK have immune anti-D (NICE, 2008). This work found that 8 of 102 (8%) of errors reported to SHOT involved women with anti-D antibodies, making them significantly more likely to be subject to an anti-D Ig error than non-sensitised women.

ii) Communication failures

This was noted across the four main SHOT error categories. Failure of staff to pass on messages was seen between laboratory staff and midwives; between medical staff and midwives; between hospital based midwives and community midwives and between midwives working in the same clinical area. Communication failures were: written, with failure to document care given; via telephone, with messages not passed on; and through misinterpretation of results due to unfamiliar or confusing documentation.

ii) Reliance on the system

Another common theme across the categories was a reliance on the system to have worked correctly. For example: In cases where blood samples were taken, failure to receive results often meant women were not followed up and when blood samples

should have been taken but were not, lack of results again meant appropriate care did not occur; when the laboratory issued anti-D Ig it was given without formally checking blood test results and when a woman had an 'RhD Neg' sticker on her notes, or attended an 'RAADP clinic' she was assumed to be RhD negative and the person administering anti-D Ig did not check her blood type formally.

iv) Reliance on others

As well as relying on the system, the midwives also made mistakes after relying on another healthcare professional. The biggest category for this was when laboratory staff issued anti-D Ig in error: midwives did not check a woman's blood results if the laboratory had issued the anti-D Ig. Likewise, when medical staff prescribed anti-D Ig, midwives did not complete their own checks before administering it.

6.4.4 Identification of key aspects of the incidents

6.4.4.1 Trigger events

As already described, the proximal cause of the error could always be narrowed down to a final, definitive, error on the part of the midwife, the 'proximal error'. However it was also possible to identify 'trigger events', events or situations without which the adverse incident is unlikely to have happened.

The following trigger events were identified:

- Expired anti-D Ig available in remote fridge
- Blood group incorrectly transcribed in notes
- Blood test results not readily available in clinical area
- Anti-D Ig that is issued by the laboratory placed in ward/clinical area fridge rather than administered immediately
- Issued anti-D Ig not collected from the laboratory
- Blood samples (especially delivery samples) not sent or incomplete/incorrect request made
- Laboratory issue anti-D Ig in error

- Blood group report misinterpreted: antibody negative misread as RhD negative
- Potentially sensitising event occurs in close proximity to RAADP administration
- RhD negative woman moves between areas e.g. Labour suite to postnatal ward to community, before blood test results available or anti-D Ig issued
- Discharge from hospital more than 72hours after delivery

6.4.4.2 Fallible practices

It was also possible to identify fallible practices (FP): policies, practices and documents that were flawed in such a way that they might lead to a trigger event. These are shown in Tables 11, 12 and 13, below, alongside associated trigger events and proximal errors.

Table 11: Fallible practices, trigger events and proximal errors: Inappropriate administration

Fallible Practice	Trigger Event	Proximal Error	Adverse Event
Accepted practice to transcribe blood group or use stickers as part of formal blood group check	Transcription error or sticker placed on wrong woman's notes	Midwife fails to complete appropriate checks	Inappropriate administration of anti-D Ig
Poor means of communication between clinical area and laboratory	Blood test results not readily available in clinical area		
Midwives do not question laboratory 'expertise'	Laboratory issue anti-D Ig for the wrong woman		
Documentation easy to misinterpret or misread	Blood group report read wrongly as antibody positive/negative instead of RhD positive/negative	Misinterpretation of results	

Table 12: Fallible practice, trigger event and proximal error: Date expired anti-D Ig

Fallible Practice	Trigger Event	Proximal Error	Adverse Event
No procedure, or flawed procedure, for checking clinical area fridge stock	Expired anti-D Ig is available in clinical area fridge	Midwife fails to complete appropriate checks	Date expired anti-D Ig is administered

Table 13: Fallible practices, trigger events and proximal errors: Omission or late administration of anti-D Ig

Fallible Practice	Trigger Event	Proximal Error	Adverse Event
Accepted practice to place anti-D Ig in clinical area fridge rather than administer it immediately	Anti-D Ig is out of sight in clinical area fridge	Midwife fails to follow up care	Omission or late administration of anti-D Ig
Reliance on blood test results or issue of anti-D Ig from laboratory to trigger action	Blood tests not sent to or received by laboratory, or form incorrectly completed (especially cord/delivery samples)		
Flawed communication pathways	Issued anti-D Ig not collected from laboratory		
Flawed communication between laboratory and clinical areas, and between different clinical areas	Woman moves between clinical areas eg from labour ward to community, prior to blood test results available and/or anti-D Ig issued		
Reliance on discharge checklist to prompt action	Discharge from hospital more than 72hours following PSE or delivery		
Staff do not understand guidelines for care	Potentially sensitising event occurs in close proximity to RAADP	Failure to follow guidelines	

6.5 Discussion

6.5.1 Strengths and limitations of this research

A major strength of this work was that the researcher had access to all anti-D Ig errors that had been reported to SHOT in a twelve month period. This data represents the most comprehensive record of recognised clinical errors involving anti-D Ig that is collated in the UK. Ironically the limitations of the research were also primarily due to the large scale collection of the data. The reports were collated by a number of different people and, due to the confidential nature of the SHOT reporting scheme, it was impossible to further question or clarify the information provided. This meant that the most significant limitation of this research was the lack of control over the data collection. The reports came from all over the UK and could each have been made by a different person. There was no information available about the person who completed the report form, nor about the initial investigation that led to their conclusions. It is possible that some of the reports were based on first-hand accounts, however others may be the result of an investigation by an individual such as a transfusion practitioner who had no midwifery or obstetric background and who did not work in the clinical area where the incident took place.

The fact that all of the reports were entered onto the same data collection form, with the same questions and the same opportunities for free text should have gone some way to addressing the potential for error. However, the content of the reports varied considerably. Some contained copious amounts of free text giving detailed explanation of the event, others provided very minimal information. The aim of this research was to analyse the data in a different, more in-depth, manner than that reported by SHOT. The content of some of the reports meant that this was challenging. In a small number of reports it was not possible to draw firm conclusions about precisely what had happened. However analysis was possible for the majority of reports and the structured approach to data analysis allowed findings to be drawn.

One of the major strengths of this study is that the errors here represent all recognised errors involving anti-D Ig that had been formally reported. As reporting is compulsory and there are strong systems for onward reporting within the NHS, it is expected that these do in fact represent the vast majority of *recognised* errors involving anti-D Ig that occurred in the UK during that twelve month period. The incidents reflect real situations and events, and despite its limitations, access to such a vital database provides a unique insight to actual clinical practice in this area.

6.5.2 Observations concerning the data analysed

The SHOT annual report has seen a gradual rise in the number of errors involving anti-D Ig in recent years. During the twelve months that this data was collated there were a total of 135 such errors reported. Given a UK birth rate of around 800,000 live births per year, and that around 16% of pregnant women have an RhD negative blood type, it is estimated that more than 205,000 doses of anti-D Ig are administered for RAADP, potential sensitising events during pregnancy and postnatal prophylaxis in the UK each year. This means that for the period of data collection, 2007/2008 an error happened in approximately once for every 1500 episodes of administration, suggesting that practice in this area is in fact very good. However, there are two important questions to consider:

- Are all recognised errors reported to SHOT?
- How many anti-D Ig errors go unrecognised?

The research completed here cannot answer these questions but it does provide some insight as to the types of errors that may be less likely to be recognised and reported. It also highlights some situations where analysis of the data suggests that there might be under-reporting. In particular the findings raise some interesting questions about the way that errors are recognised.

Laboratories are very process driven and have procedures in place that increase the likelihood of identifying errors. However in clinical areas it is not routine practice to actively search for errors. It would seem that when there is no laboratory

involvement in the process of anti-D Ig administration errors might be less likely to be recognised. The findings of this research show broadly similar numbers of errors detected by laboratory and clinical staff. On the face of it this contradicts the theory that errors are less likely to be detected by clinical areas, however looking more closely at the types of error reported to SHOT questions are raised about clinical areas recognition of errors. One example of this is an error where anti-D Ig was deliberately omitted following a potentially sensitising event during pregnancy due to a misunderstanding of guidelines. This type of error would only be recognised and reported if another clinician reviews the case and recognises that an error has been made. In another example, if postnatal anti-D Ig is omitted for a woman in an area where anti-D Ig is given from clinical stock, it is easy to see how such an error would go unrecognised. The people who are involved are unaware that they have made an error and there is no mechanism in place to bring it to light. This observation is supported by the finding that none of the errors reported in the late/omitted category involved anti-D Ig held in clinical stock. There is no plausible explanation as to why an error would be more likely using anti-D Ig issued by the laboratory. What is most likely is that when anti-D Ig is held in remote stock it is easier for the person making the mistake to remain oblivious to their error as there is no laboratory involvement that might uncover the error.

Data collated by SHOT suggests that very few errors involving anti-D Ig are made, however it is important to consider whether, in fact, many errors are difficult to recognise and go unreported. The 2008 annual SHOT report acknowledges that they receive “only a fraction of the possible reports” (Taylor et al, 2009, Pg2), but consider that those they do receive reflect overall trends. Further research is required to explore whether the SHOT error reports do in fact reflect the actual trends of type of error involving anti-D Ig. Maternity units should also consider implementing procedures that would detect such errors, particularly when anti-D Ig stock is held in clinical areas.

6.5.3 Midwives and anti-D Ig errors

The research described here considered SHOT error reports concerning anti-D Ig from the point of view of midwives. By excluding errors where there was no midwifery involvement, for example errors resulting from laboratory failures that would have been impossible to identify in the clinical area, or those solely by medical staff and nurses working in gynaecology or accident and emergency departments, the focus of the research became midwives. This meant that it was possible to identify the errors that hold particular significance for midwifery practice, the ways that midwives contribute to errors and what might be done, by midwives, to reduce the likelihood of recurrence.

The simple classification of errors essentially repeated categorisation of errors undertaken by SHOT, but only included those errors where a midwife was involved. It was important to recategorise the errors as SHOT reported a number of errors as 'laboratory' that did in fact involve midwives. A common example of this was cases where the laboratory issued anti-D Ig in error to an RhD positive woman, but the midwife administered it without checking the woman's blood type. Although on the face of it this would seem like a simple error on the laboratory part, it was within the midwife's power to prevent administration of anti-D Ig through completion of routine checks.

The research sought to identify the proximal cause of the errors, and found just four, one of which was present in every error report. These were:

- Failure to complete appropriate checks
- Failure to follow up care
- Misinterpretation of results
- Failure to follow guidelines

They represent the final act or omission that allowed, or led directly to, the error happening. Although the errors were made by a midwife, it is important to reiterate that in most cases there were a number of significant contributing factors that

influenced the error. Often those were organisational factors that directly influenced the likelihood of an error occurring. It is also notable that the midwife who administered anti-D Ig assumed ultimate responsibility even if there was a line of process involving others who also made mistakes. This research only looked at errors that involved midwives, and so the proximal errors here were always midwife errors. The same factors could easily apply to other professions were they scrutinised in the same manner.

The proximal errors, or causes, were often influenced by other factors, but in themselves they are an important tool in understanding how errors happen. In particular they are a useful starting point for midwives to use in reflection on why the error happened and how that relates to her professional responsibility. The proximal error may represent an event that is very difficult to influence, for example simple human error such as forgetting to check a detail. However, there will be other cases where checks were not carried out because policies or procedures were not fully understood or were unfamiliar. Equally, it may be that the midwife has an element of shared responsibility with her employer, who may have an established culture of practices that influenced the error, or shared responsibility with a colleague who was involved in an earlier part of the process. Using the proximal errors as a foundation for understanding what happened is an important way for an individual to address the event and consider how recurrence can be avoided.

When discussing this work, it is useful to consider the errors according to type. In the following section (6.5.4), within those headings, the findings are discussed in relation to analysis of ‘proximal errors’ and the detailed description of the errors.

6.5.4 Inappropriate administration of anti-D Ig

Inappropriate administration was the most common anti-D Ig error made by midwives, and almost all of the cases were due to midwives failing to complete appropriate checks. Although some errors in this category also involved other staff, for example laboratory staff who issued anti-D Ig in error or medical staff who prescribed anti-D Ig for the wrong woman.

The cases where anti-D Ig was administered inappropriately raise questions about why the midwife went ahead with administration of the anti-D Ig and how she involved the woman in the decision to administer it. A common reason for inappropriate administration of anti-D Ig was failure to complete adequate identification checks prior to administration. This raises the question of whether midwives understand policy and procedure in relation to these checks, and also of how midwives view administration of anti-D Ig. Do they view it as similar to administering medication, or the more involved process of checking prior to administration of a blood transfusion? Their views on this may influence the rigour with which they approach checks. The midwife is responsible and accountable for her actions when administering anti-D Ig. It is her professional responsibility to ensure that she is familiar with policies and procedures, including those checks that are required prior to administration of anti-D Ig. She should also understand the reason for giving anti-D Ig in a specific situation.

The woman herself should be included in the process of offering and any subsequent administration of anti-D Ig, in particular identifying herself as the correct recipient, but also in explaining the need for anti-D Ig and gaining verbal consent prior to administration. The midwives' code states that 'you must ensure that you gain consent before you begin any treatment or care' (NMC, 2008, Pg3). Administration of anti-D Ig to women who are RhD positive, raises important questions about how the midwife involved the woman in either of those aspects of the process. Exploration of this was beyond the scope of this research but is an important area to consider for future work.

Another common reason for giving anti-D Ig inappropriately was a transcription error. These errors included writing the woman's blood group in the notes, and the use of stickers on the notes to convey blood type. As already discussed, it is the midwife's professional responsibility to complete the necessary checks prior to administration of anti-D Ig. However, if it is common practice within an organisation to rely on informal means to convey blood type, then some of the responsibility for the error must be borne by that organisation. This would be an example of what

Reason (2000) would describe as a ‘latent condition’, and what in this research is described as a ‘fallible practice’. They are often relatively easy to rectify and this greatly reduces the likelihood of an error, by filling another hole in the Swiss cheese. However this requires effort at organisational level.

There were a very small number of cases in this category where the midwives administered anti-D Ig in a situation where they were unable to formally confirm the woman’s blood type, but thought it to be RhD negative. On the face of it this seems irresponsible, however the reports suggest that the midwives had made a considered decision to administer the anti-D Ig. An example of this was a situation where a woman had a poor history of attendance for antenatal care. The midwife was faced with a situation where she was unable to confirm the woman’s blood type formally, but knew that she might not attend again to receive anti-D Ig. In this case it would appear that the midwife made a decision to provide care out with standard policy and procedure as she felt it was in the best interest of the woman. Unfortunately the woman was in fact RhD positive and the anti-D Ig administered was unnecessary. This situation raises the dilemma that a midwife might face between her professional accountability and her responsibility to her employer to provide care within their guidelines. Her professional responsibility is to provide care ‘using her professional knowledge and based on evidence for best practice and in the woman’s best interests’ (NMC, 2008, Pg6). In the situation described above a midwife would have to be very confident of her knowledge and practice to act in a way that she believed was in the woman’s best interest but which was contrary to her employer’s policy. It was not clear in this case why the midwife could not formally check the woman’s blood type as these should be readily accessible. There is limited information available on the particular circumstances of this event, however in such situations it may be worth considering the organisation’s responsibility to ensure that staff are able to access results readily.

It is interesting to note that within this category of error there were a number of women with immune anti-D antibodies who received anti-D Ig. Anti-D Ig is given to prevent formation of immune anti-D antibodies and so there is no point in giving it to

women who are already sensitised. Doing so exposes her unnecessarily to a blood product. Only around 1-2% of RhD negative pregnant women are sensitised, but around 8% of the errors involved women who were sensitised. It is not clear from the findings here why this should be the case. It may simply reflect failure to complete appropriate checks prior to administration of anti-D Ig, but also raises questions about midwives' knowledge and understanding of the significance of anti-D antibodies and perhaps of the ways that they are reported and documented within maternity notes.

6.5.5 Omission or late administration of anti-D Ig

This category of error is particularly important as they are the type of error that are most likely to lead to maternal sensitisation. As already mentioned there were only 10 cases where anti-D Ig was omitted altogether, but there were 34 where it was given late, raising the question of whether this is a category of error that is particularly susceptible to underreporting due to failure to recognise that an error has been made. It also raises the question of whether the errors reported here represent those most commonly made, or whether they represent those most likely to be noticed and reported.

The main proximal error in this category was 'failure to follow up'. This makes it particularly difficult to pinpoint an individual who was responsible for the error, and to determine exactly how the error came about. NHS maternity care is structured in such a way that there is unlikely to be continuity of carer as a woman is transferred between clinical areas following delivery. The move from labour suite to postnatal ward and then home to the community service might all happen during the 72 hours following delivery when anti-D Ig should be offered and administered. During pregnancy a woman may receive her routine care from a number of different midwives working in the same team, and from other midwives and obstetricians should she experience a PSE and attend hospital. Given the potential for a large number of carers, it is unsurprisingly the majority of errors in this category have failures in communication as a significant contributor.

There were a very large number of cases in this category of error where anti-D Ig was simply not collected from a laboratory area fridge, or was delivered to the ward or clinical area and left unnoticed in the fridge. This highlights serious failures in communication: both documentation and direct communication between laboratories and clinical areas, or between midwife and midwife. It also reinforces the need for strong formal procedures to ensure that administration of anti-D Ig is not overlooked when responsibility for care is passed between midwives working in different areas or covering different shifts within the same area.

Midwives' reliance on the system to highlight the need for intervention was also evident. Examples of this include a situation where sending delivery blood samples to the laboratory leads to the laboratory issuing anti-D Ig, with its delivery to the ward being the prompt for midwives to administer it. When delivery samples were not received by the laboratory, this prompt was lost and anti-D Ig not administered. Midwives' hold responsibility for ensuring that a woman receives appropriate care, however in an organisation that sees a number of different midwives assuming responsibility for a woman's care within the short window of time that anti-D Ig should be offered and administered, it may not always be clear which particular midwife that responsibility lies with. In such situations organisational factors such as the quality of documentation and the use of procedures such as handover and discharge checklists all assume increased importance. Here the organisation has significant influence over the provision of care as it is responsible for the way that care is organised and for policies procedures and documentation that are in place to support staff in the provision of care.

Misinterpretation of results was the other 'proximal error' found in this category. Some of the cases may have been due to human error, however analysis also raised questions about midwives' knowledge and understanding of the issues surrounding the requirement for anti-D Ig and its administration. Additionally a number of error reports in this category demonstrated the direct impact that documentation may have on anti-D Ig errors. In those errors the paper laboratory report documented RhD status as 'positive' or 'negative' in close proximity to an antibody test result also

reported as ‘positive’ or ‘negative’. The design of this documentation was such that it contributed to the error because of the high risk of misreading blood type as antibody status, and vice versa.

In common with the errors already discussed in the inappropriate administration category, there were a number of errors where blood test results were wrongly transcribed in notes. These errors further illustrate an organisational culture in some maternity units where the midwives’ are willing to administer or omit anti-D Ig based on transcribed notes rather than checking the formal blood bank report or telephoning the laboratory directly.

Interestingly anti-D Ig was most likely to be given late, or omitted altogether, during the postnatal period, despite the fact that anti-D Ig is given more often during pregnancy. As postnatal anti-D Ig is more likely to be issued directly by the laboratory, rather than given from clinical stock, it may more likely that a postnatal error is recognised and reported. Involvement of the laboratory in the process, coupled with the use of discharge checklists may mean that postnatal errors are more likely to be recognised and reported to SHOT. This provides further evidence that there may be under reporting of anti-D Ig errors to SHOT.

6.5.6 Wrong dose of anti-D Ig administered

The errors where a wrong dose of anti-D Ig was administered broadly reflect the ways in which errors occurred in the other categories. Failure to complete adequate checks was again the most prominent ‘proximal error’. In addition failures in communication and reliance on others to have completed their part in the process correctly were strong themes.

The case where the wrong dose of anti-D Ig was given intentionally is interesting. It again raises the potential for under reporting of this type of error as those involved believed that they were acting appropriately. It also illustrates a case where the situation was complicated by a potentially sensitising event during pregnancy occurring around the same time that RAADP was required. One of the reasons given

to help explain the steady rise in anti-D Ig errors reported to SHOT is the widespread introduction of RAADP and the subsequent increase in number of women receiving anti-D Ig during pregnancy. This research found that RAADP was involved in just 12% of error reports, despite accounting for as many as half of all cases of administration of anti-D Ig. As such RAADP would not appear to be a significant factor in the increase of reporting to SHOT. It may be that practice is particularly good around this very routine aspect of clinical practice, but it is worth noting that most RAADP is given from clinically held stock. This means that it is another aspect of clinical care where an error, particularly an omission, may easily go unnoticed and unreported.

6.5.7 Date expired anti-D Ig

This category of error had only three cases and it is difficult to draw any firm conclusions from them. All three cases happened as a result of failure to complete appropriate checks, and all three involved anti-D Ig from clinically held stock. This raises the organisational level issue of controlling stock held clinically to ensure that date expired anti-D Ig is not available for use. It also raises, yet again, the question of whether there is potential here for failure to recognise an error. Common sense would dictate that the three cases where the midwives realised their error after administration of anti-D Ig are unusual. It would seem far more likely that if the expired date was not picked up at a check prior to administration, it would remain unnoticed and so unreported.

6.5.8 Themes common to all four categories of error

There were a number of common themes that ran through all four categories of error. They are discussed within those categories, but it is worth reiterating them here. They include failures in communication, the potential for under-reporting of errors and reliance on both the system to prompt action, and on other staff to act appropriately. Although the error could always be narrowed down to a final ‘proximal error’, it was clear from analysis of the error reports that there were a

number of factors out with the midwives' control that influenced the likelihood of an error occurring.

In all four of the error categories responsibility for the error often fell between the organisation within which the midwife provided care, and the midwife herself. The following section discusses the key aspects of the error report: the clinical situations that might give rise to an error and the organisational factors that influence them.

6.5.9 Identifying key aspects of the reports: trigger events and fallible practices

This aspect of the analysis and findings has the most direct clinical relevance for midwives. By highlighting 'trigger events' and the 'fallible practice' that can lead to its manifestation, midwives, medical and laboratory staff, and the organisations that they work for, can identify such factors within their own areas of practice. Through addressing these it should be possible to greatly reduce the risk of an error occurring. The theory for this aspect of the analysis was based on the work of Reason (2000). In his anatomy of an organisational accident he describes failures at organisational level cascading through to a department to create conditions that promote occurrence of errors.

This research identified a number of specific fallible practices and trigger events (Tables 11, 12 and 13) with the clinical detail of these discussed in relation to the analysis of detailed description of the error reports (above). It is anticipated that identification of specific fallible practices and trigger events can be used by midwives and managers to examine whether similar factors and situations are present within a particular organisation and clinical area. They will also be helpful in structuring an investigation into future errors, enabling the investigator to use this framework to identify factors that might be changed.

The most significant theme to emerge from this analysis was the emphasis on shared responsibility between the employing organisation, and the midwife employee. The organisation has a responsibility to develop and support working practices, cultures, documentation, processes and procedures that limit the scope for error. Likewise the

midwife must address her professional responsibility and develop the knowledge and skills to underpin her practice. This should include understanding of the rationale for administration of anti-D Ig in whatever clinical situation arises. It also encompasses familiarisation with relevant policies and procedures, including the appropriate checks to be completed, before administering anti-D Ig.

6.5.10 Informing the next piece of work: focus group research to gain a midwifery perspective

This study, secondary analysis of SHOT anti-D Ig error reports, and the previous work, the RAADP survey, both raise important questions about midwives practice in relation to anti-D Ig. These questions and issues are outlined here with the intention that they will inform the next piece of research: focus groups to gain a midwifery perspective. The focus group work is intended to explore these issues further with the aim of clarifying some of the questions raised.

Midwives' knowledge and understanding about anti-D Ig and what their sources of information, education and training are is incredibly important. Analysis of the SHOT error reports highlights the need for midwives to underpin their practice with sound knowledge and understanding of clinical situations and rationale for care. Additionally they must understand the local and national policies, procedures and practices which safeguard against error and steer appropriate care. There were a number of errors where midwives' lack of knowledge and understanding about anti-D Ig itself, or about policy and procedures, may have influenced events. Midwives also require good knowledge of the issues involved in order to facilitate informed decision making, particularly in light of the variations in practice and in the variable quality and content of written information that was uncovered by the RAADP survey

The RAADP survey found that most organisations provided education or training at the time that RAADP was implemented, although it did not explore what form that took or the impact it had. Midwives' have a professional responsibility to maintain their knowledge and skills, however their employers also have responsibility to support them in maintaining their skills, and to ensure that they have the knowledge

and skills necessary to practice safely and effectively. It is considered relevant to explore with the midwives what form the education they receive takes, how they feel about the education they access, what support they receive from their employer in this respect and whether they feel it is sufficient to meet their learning needs. In addition the researcher would like to explore their level of knowledge on some of the issues pertinent to facilitation of informed decision making and provision of appropriate clinical care.

Another important theme to emerge from the analysis of the errors reported to SHOT was communication. This encompassed communication between midwives in different clinical areas, laboratory staff, medical staff and pregnant women with RhD negative blood group. It also extends to documentation used. It was considered another important area for further exploration and will be addressed within the focus groups.

The analysis of the SHOT error reports raised important questions about the recognition of anti-D Ig errors by clinical staff. The focus group research will also be used to explore further what the midwives know about the SHOT reports, and also if they understand the process for reporting an error to SHOT.

The most important theme to emerge from the findings of the research already undertaken is midwives responsibility and accountability in relation to anti-D Ig. As already stated, this responsibility extends to their knowledge and understanding of the issues involved as well as their clinical skills. It also encompasses awareness of policies and procedures that should be undertaken to ensure safe and effective practice and minimise the risk of error. In the analysis of the SHOT error reports, this was apparent across all categories of error, but is complicated by the organisational factors that imposed on the way that they work. There were a number of situations where organisational factors significantly influenced midwives' practice, yet their professional accountability remained. Similarly, the survey on implementation of RAADP policy found considerable variation in that policy throughout the UK. This may impact on midwives' practice, in particular it highlighted some situations where

midwives' personal and professional responsibility and accountability may be at odds with her obligation as an employee to fulfil her employer's organisational responsibilities. Midwives' must maintain professional responsibility but balance this with their responsibility as an employee working for an organisation that has its own policies and subsequent responsibilities that will influence midwifery practice.

The questions and issues outlined above were used to inform the research presented in the following chapter: Chapter seven.

Chapter 7: Focus group research to gain a midwifery perspective

7.1 Introduction

The overall aim of the third piece of research was to explore midwives' perspectives of the care provided for pregnant women with an RhD negative blood type. The objectives were to elicit their opinions and experiences of topics that had been identified through published evidence and the research already undertaken in Chapters five and six. There were four broad research questions:

1. How do midwives understand their responsibility when offering and administering anti-D Ig?
2. Do midwives understand the risks and benefits of anti-D Ig?
3. Are midwives able to recognise and report an error involving anti-D Ig in a manner that will lead to onward reporting to SHOT?
4. What education and/or training do midwives receive in relation to anti-D Ig?

7.2 Choice of method

A number of methods were considered, including in-depth interviews and survey. However, as described in Chapter four, section 4.1.3, a qualitative approach was deemed most appropriate, and focus group interviews were the data collection method of choice.

There is a strong history of using qualitative approach in nursing and midwifery research and qualitative methods lend themselves to exploration of many of the areas that are of particular interest to nurses and midwives. Within the midwifery profession there are many examples of focus group interviews used as method of eliciting qualitative data. In particular the method has been used to describe midwife and student midwife experiences, the factors that influence the ways in which they deliver care and to describe midwifery culture in particular settings, context or in relation to specific situations or practices (Brooke-Read et al, 2012, Teate et al, 2012, Jones and Wylie 2008, Fox-Young et al,2012) . These examples include focus groups

used as the sole method of data collection, and other studies where they are used in conjunction with other methods.

Focus group research can be very specific and focus in on a relatively narrow topic area. Jones and Wylie (2008) for example, used focus groups to elicit very specific information from student midwives about stress related to clinical placements. Other researchers have started off with a much broader topic and used focus groups to elicit more specific themes within the broader topics in order to inform further research. There are also numerous recent examples of midwifery research that uses focus group research as one aspect of a larger study. For example Teate et al (2012) used focus groups within a mixed methods approach. In their research they collected data using focus groups, surveys and checklists and combined this to describe midwives' experiences of becoming pregnancy centring facilitators. Another example is that of Brooke-Read et al (2012) who combined data collection through survey research and focus groups to describe student midwives' experiences of using electronic health records.

Barbour (2005) describes a number of research studies that use focus groups to research healthcare professional's attitudes, opinions and experiences of education initiatives. Barbour (2005) notes that focus groups are particularly appropriate when researching a previously unexplored topic, or one that is poorly understood or ill-defined, and often has the ability to "reach parts that other methods cannot reach" (Barbour, 2005, P 745). An example given by Barbour (2005) is the research of Saidi and Weinding (2003) where focus groups were used to evaluate a new education initiative for paediatricians. The focus groups were used to identify barriers to accessing the initiative and establish staff groups with particular difficulties. The method also allowed the researchers to elicit more subtle, but equally important ways in which the paediatricians considered that their clinical practice had changed as a result of the educational initiative (Barbour, 2005).

Focus group interviews comprise group discussion between individuals, guided by a moderator using a topic guide developed from a well-defined research objective. A

key feature is facilitation of discussion on the topic of interest, and a key characteristic of focus group interviews is group interaction. Capitalising on communication between research participants allows the subjects to talk to one another "asking questions, exchanging anecdotes and commenting on each other's experiences and points of view" (Kitzinger, 1995, Pg 299). For this research the broad topics of interest had been identified, but the research aim was to discover actual views and experiences of midwives within those topic areas. For this reason the interaction between participants in a group interview setting was seen as an advantage of using this method, although it was not the primary incentive. The potential for group discussion on the topic areas was considered likely to produce richer information than could be gained through one on one interview or questionnaire research, it also offered an opportunity for the midwives to agree or disagree with each other's perspectives and points of view. In this way providing a form of validation of the information gained, at least within the context that group of midwives.

A potential disadvantage of this method is that some people may be uncomfortable expressing their views or describing their experiences in front of a group. In particular Kitzinger (1995, Pg 299) states: "the articulation of group norms may silence individual voices of dissent." This could be pertinent in a setting where midwifery colleagues know one and other and already have an established formal or informal hierarchy. In this research this might be especially significant as the topics to be explored included areas of practice that might be regarded as contentious or 'against policy'. However Kitzinger (1995) also considers that groups can provide mutual support in expressing feelings that they share but consider contentious. Barbour (2005) also describes focus groups as an inherently flexible method of data collection and believes they have an ability to dilute the power balance between researcher and subjects through the naturally occurring peer group, encouraging uninhibited discussion.

For this particular research an advantage of using focus group interviews was that they allow data from multiple respondents to be collected in a much shorter time than

individual interviews would. At the time that this study was conducted, the NHS in Scotland was under considerable financial pressure. Persuading managers to allow staff time to participate in non-clinical sessions can be extremely difficult. It was certainly easier to arrange one-off sessions that saw a number of staff attend together. In addition the group interviews were held, deliberately, in geographically widespread sites. This meant that the researcher had to travel long distances to attend the sessions and holding one session in a morning or afternoon, rather than a number of sessions to conduct individual interviews, offered better use of the limited time and resources available. These factors combined to make this method the most practical method of collecting data from this group of healthcare professionals within the resource constraints of this project.

Although there were some potential problems with this method, the researcher felt that the advantage of gaining the views of a number of midwives, coupled with potential for some discussion and clarification within a group, outweighed those disadvantages. In order to mitigate inhibition among group participants, steps were taken to foster an atmosphere where the midwives felt able to participate freely and without censure

7.2.1 Focus group interview method applied to this research

Focus group interviews were considered the most appropriate method of data collection for this research. However due to the specific nature of the information to be collected and the limited time available for the sessions, it was recognised that within the focus groups a structured approach with less emphasis on discussion and more emphasis on answering specific questions would be necessary. Oppenhiem (1992) describes group interviews as useful method when the topic is relatively straightforward, but cautions that a number of issues should be considered in order to facilitate an effective session. In many respects group interviews are similar to focus groups, with Polit et al (2001, Pg 462) defining focus group interviews simply as “an interview with a group of individuals assembled to answer and discuss questions on a given topic”. The method used for this research held much in common with focus

group research but was very structured, with more emphasis on the midwives answering questions from a predetermined 'topic guide' and less on generating in-depth qualitative data from any discussion developing from those topics. The level of structure the moderator would impose on the session was recognised as important when considering this method. Morgan (1997) considers that a more structured approach is especially useful when there is a strong pre-existing agenda for the research. Another advantage of a structured approach is that it may help groups at different sessions discuss the issues in a relatively comparable fashion.

The use of a topic guide was an important tool to achieve a structured approach to the method used and its development was regarded as key to achieving the aims of the research. The topic guide consisted of both stand-alone questions and scenarios with associated questions (Appendix 5). The scenarios were based on actual SHOT anti-D Ig error reports and were used in an attempt to illustrate clinical care in a way that was relevant to the midwives, providing a platform from which the midwives could answer questions about the topics of interest. Kitzinger (1995) describes a range of group exercises that may be used to facilitate discussion or return to topic and states that ideally the discussion should be tape recorded and transcribed, allowing the moderator to concentrate on their task rather than taking notes. These factors were taken into consideration when planning the focus group sessions.

There was a well-defined research objective, with a focus on specific topics and it was hoped that the use of focus group interviews would provide data to enhance understanding of these particular issues and topics and identify other as yet unapparent issues that are relevant to the midwives, to their clinical practice and to their relationship with the women they provide care for.

7.3 Practical considerations in the use of focus group interviews

7.3.1 The role of the moderator

There is agreement among authors that the role of the moderator is key to the success of focus group interviews, with the ability to put people at ease, encourage them to talk to each other and foster an atmosphere of respect and openness regarded as crucial. Oppenhiem (1992, pg79) suggests that when conducting group interviews the leader should be as non-directive as possible while maintaining control of the group. This hinges on an ability to adopt a form of "structured eavesdropping" where the researcher guides the participants to talk about the topic of interest without participating in the discussion themselves (Kitzinger, 1995).

In this instance the researcher did not have direct experience of conducting group interviews or of focus group research, but the importance of the role of the moderator was recognised and a number of steps were taken to prepare for this. These included attendance at a three day course on qualitative research methods that offered detailed insight into focus group interviews as a data collection method in healthcare research. The course also provided an opportunity to discuss the proposed research in detail with qualitative researchers who had experience of using this research method.

An important aspect of the researcher's role as a Transfusion Specialist Midwife with the Scottish National Blood Transfusion Service was the development and facilitation of face to face learning for midwives and medical staff through seminars and workshops. This meant that the researcher was experienced in conducting group learning and facilitating discussion on specific topics. These sessions were particularly useful as the researcher was able to utilise time at the end of a number of such sessions to 'practice' moderator skills and facilitate discussions on topics similar to those that would be explored formally through the focus group interviews. This allowed development of moderator skills prior to undertaking the actual research.

7.3.2 Resources

Morgan (1997) warns that focus groups are potentially expensive with costs including: moderator's salary, rental of research site, travel to site, payments to participants, and producing and transcribing the tapes. The financial resources available for this research were extremely limited and played a significant part in planning the group interviews. The researcher was the moderator, so no salary payment was necessary, similarly the researcher transcribed the recordings of the sessions. There were no funds available to pay for either renting a research site or paying participants to attend. For this reason it was decided to seek permission from Heads of Midwifery to hold the group interviews at the chosen NHS maternity units and for midwives to attend during work, rather than their own, time.

7.4 Arranging and conducting the sessions

Two focus group interviews were conducted and it was decided that the participants should be midwives currently practising within NHS maternity units. The two maternity units were chosen as they seemed typical of Scottish maternity units, both were similar in size, with between 3500 and 4000 deliveries per year. They did however serve quite different populations: Maternity Unit A being a maternity unit within a general teaching hospital, serving both urban and semi-rural populations and received tertiary referrals of higher risk pregnancies. Maternity Unit B was a stand-alone maternity unit several miles from the nearest general hospital and offered lower risk care, serving a mainly rural population.

The Heads of Midwifery at the chosen maternity units were contacted, provided with an outline of the research, a copy of the letter obtained from South East Scotland Research Ethics Committee (Appendix 3) concerning the ethics of the research, and permission was sought to conduct a group interview within their unit. In both cases the Heads of Midwifery then provided the contact details of a senior midwifery manager in their unit with whom the researcher should liaise to arrange the sessions.

7.4.1 Sampling

Morgan (1997) considers that random sampling is rarely practical within focus group interviews due to the small number of participants, meaning that it is highly unlikely that you would ever achieve a truly representative sample of your population. He does however state that group composition should "ensure that the participants in each group both have something to say about the topic and feel comfortable saying it to each other" (Morgan, 1997, p36). Background variables are important in developing a group that will feel free and able to speak freely. In this instance the main factor that might inhibit the group was considered to be their work relationship, in particular whether any of the midwives were managed by another participant. It was important that all of the midwives should feel free to describe the actual way they practice and their true views on a number of topics and issues, some of which might be influenced by line managers.

In the event both of the midwifery managers who were helping arrange the group interviews expressed concern about being able to release midwives from their clinical duties to attend sessions. For this reason practical considerations dictated the sampling strategy to a great extent. Following detailed discussion with them both, it was decided that they would set a date, time and venue for the sessions and ask midwives from community and hospital settings to attend if they were willing and able to do so at the time. The researcher also offered to hold an education session on anti-D Ig following each group interview.

Written information outlining what was involved in the group interviews and the research as a whole was made available to the midwives who might participate. Oppenhiem (1992) suggests that group interviews might have between eight and twelve participants and Freeman (2006) describes a typical focus group as consisting of between 6 and 10 participants. However, Kitzinger (1995) describes an ideal number of participants as between four and eight people. It was decided that the focus groups should go ahead with a minimum of four and a maximum of ten participants, midwifery managers would not be invited to participate.

7.4.2 Format of the group interviews

Literature review and previous research had identified a number of topics that the researcher wanted the midwives to discuss during the group interviews. Factors out with the researcher's control meant that there would be fairly limited time available for discussion and it was important that the identified issues were discussed during the sessions. For this reason the plan was to conduct structured group interviews rather than traditional focus groups.

A topic guide was developed, a copy of the topic guide is in Appendix 5. It incorporated a number of exercises that included scenarios, based on actual SHOT incident reports, and questions about those scenarios to be used to elicit information about the relevant topics.

The moderator's topic guide for Maternity Unit A consisted of:

- Openers/information: intended to welcome the participants, explain the format and purpose of the session, put them at ease and reassure them of confidentiality.
- Risks and benefits of anti-D Ig: scenarios, exercises and questions designed to elicit views on the risks and benefits of anti-D Ig
- Identification of errors: Questions of anti-D Ig errors and reporting mechanisms
- Professional responsibility: A scenario and exercises designed to elicit views on their understanding of professional responsibility
- Education: questions to prompt discussion on their education and training in relation to anti-d Ig and care of RhD negative pregnant women

The topic guide was a 'guide' and the moderator did not always stick rigidly to it, for example if questions had already been addressed through earlier discussion or where time was short and there was a need to prioritise some questions over others.

7.4.3 Conducting the group interviews

In both maternity units the sessions took place in a quiet room within the hospital, with chairs placed around a large table or group of tables pushed together. It was

important to create an atmosphere that was relaxed and comfortable, and one in which the midwives were able to talk freely without fear of recrimination or ridicule.

Refreshments were provided by the moderator at the beginning of each session and the midwives were encouraged to relax and chat informally amongst themselves and with the moderator prior to the start of the session. The researcher then introduced herself and gave a brief overview of the purpose of the session, and the participants had an opportunity to ask questions. All participants were encouraged to be as open and honest as possible even if they disagreed with their colleagues. At this point they were also offered the opportunity to leave if they wished. It was ascertained that none of the midwives was each other's line manager and that they worked in diverse areas of practice but all might be required to administer anti-D Ig and/or advise a woman regarding anti-D Ig. The midwives were also told that information was being collected anonymously and anything said during the session would be treated confidentially. They were informed that the moderator intended to record the session using a digital sound recorder, and were asked if they had any objections. None did.

Due to restrictions on the midwives' time, the sessions were planned to last for one hour. At the end of the session all of the midwives were asked to complete a very short questionnaire providing details of their length of time working as a midwife, whether they had administered anti-D Ig in the past 6 months and if they had been directly involved in an anti-D Ig error. It also provided room for free text where they could add any further comments about the topics discussed during the sessions.

7.5 Data analysis

The data analysis was qualitative and thematic in nature with aspects of the framework approach used to provide a more focussed and structured approach to the analysis. The framework approach was developed in the 1980's by social policy researchers. Originally a tool for applied policy research (Ritchie et al, 2003) it has been used in healthcare research (Smith and Firth, 2011). The framework approach is a structured and focussed approach that allows a systematic analysis of qualitative data and in this way it "contrasts with entirely inductive approaches such as

grounded theory" (Smith and Firth, 2011). Srivastava and Thomson (2009) believe that the framework approach is best adapted to research that has specific questions. Pope et al (2000, Pg 116) also describe the framework approach as starting "deductively from pre-set aims and objectives". The main aim of this research was to answer specific questions that had been identified through the two previous pieces of research, described in Chapters five and six, and through literature discussed in Chapter three. Although the framework approach is more often associated with analysis of large data sets it was deemed appropriate to base the analysis on this framework in order to impose structure. Using thematic analysis with this structured process was considered to be a method of analysis that would allow the researcher to focus on those issues and questions, but would also allow identification of any new themes that became apparent.

Another potential advantage of the method was that it would allow qualitative exploration of data but also enable the researcher to "track decisions, which ensures that the links between original data and findings are maintained and transparent, enhancing the validity of the findings" (Smith and Firth, 2011, g 62). Thorne (2000, Pg 70) goes as far as to say that many researchers have concluded that "systematic, rigorous, and auditable analytical processes are among the most significant factors distinguishing good from poor quality research".

The framework approach incorporates interconnected stages, with description of the stages varying between authors. The process was adapted to suit the aims and objectives of this research and the stages used here were:

1. Familiarisation with the data, leading to identification of initial categories, assignment of pieces of data to those initial categories and refinement and establishment of key themes.

2. Refinement of the initial categories and development of final themes and core concepts.

3. Understanding the core concepts and final themes, in order to explain them in relation to other themes and in the context of what is already known about the subject.

Definition of the terms used:

Key Themes: *Important themes within the data, some of which were pre-determined by the researcher*

Initial Categories: *Represent themes and concepts derived from similar sections of transcript*

Refined categories: *More focussed categories, derived from the initial categories*

Final Themes: *Themes that describe data in relation to a particular key theme*

Core concepts: *Overarching ideas or concepts that permeate the research as a whole and allow the findings to be placed in a wider context*

The first stage of the analysis was familiarisation with the data and development of key themes and initial categories. The recordings of the sessions were listened to several times and were then transcribed into Word documents. This took place as soon as possible following each focus group interview so that the sessions, and participating midwives, were fresh in the researcher's mind. The transcription was undertaken by the researcher which was time consuming but had the advantage of further enhancing familiarisation with the data collected. The transcripts were then read several more times, allowing the researcher to become very familiar with the data.

The researcher had previously identified a series of key themes, topics of interest related to the key questions within the research aims. Initially these were: risks and benefits of anti-D Ig; identification of anti-D Ig errors; professional responsibility and accountability and education and training. However, the familiarisation process led to refinement of the 'pre-determined' key themes and emergence of additional key themes. This process also led to identification of initial categories: "a list of what

appear to be important themes and concepts within the data" (Ritchie et al, 2003, Pg222).

The next stage was to organise the data, and passages of text that related to each of the key themes and the initial categories. This was done through what Bernard (2000) describes as 'pawing' through the text, marking passages with different coloured pens. An example illustrating an excerpt of transcript with relevant key issues and initial categories is illustrated in Table 14, below.

Table 14: Allocation of an excerpt of transcript to key themes and initial categories

<table>
<tr><td colspan="4">Excerpt of transcript:
MW3b: “So it {RAADP} isn’t one of the big important things that you’d really think ‘oh we have to get her in its desperately important’. We were here the years when they never got it before”
MW1b: “Yes, that’s right”
MW3b: “Unless they had a bleed</td></tr>
<tr><th>Section of transcript</th><th>Preliminary thoughts</th><th>Initial Categories</th><th>Key Themes</th></tr>
<tr><td>So it isn’t one of the big important things…

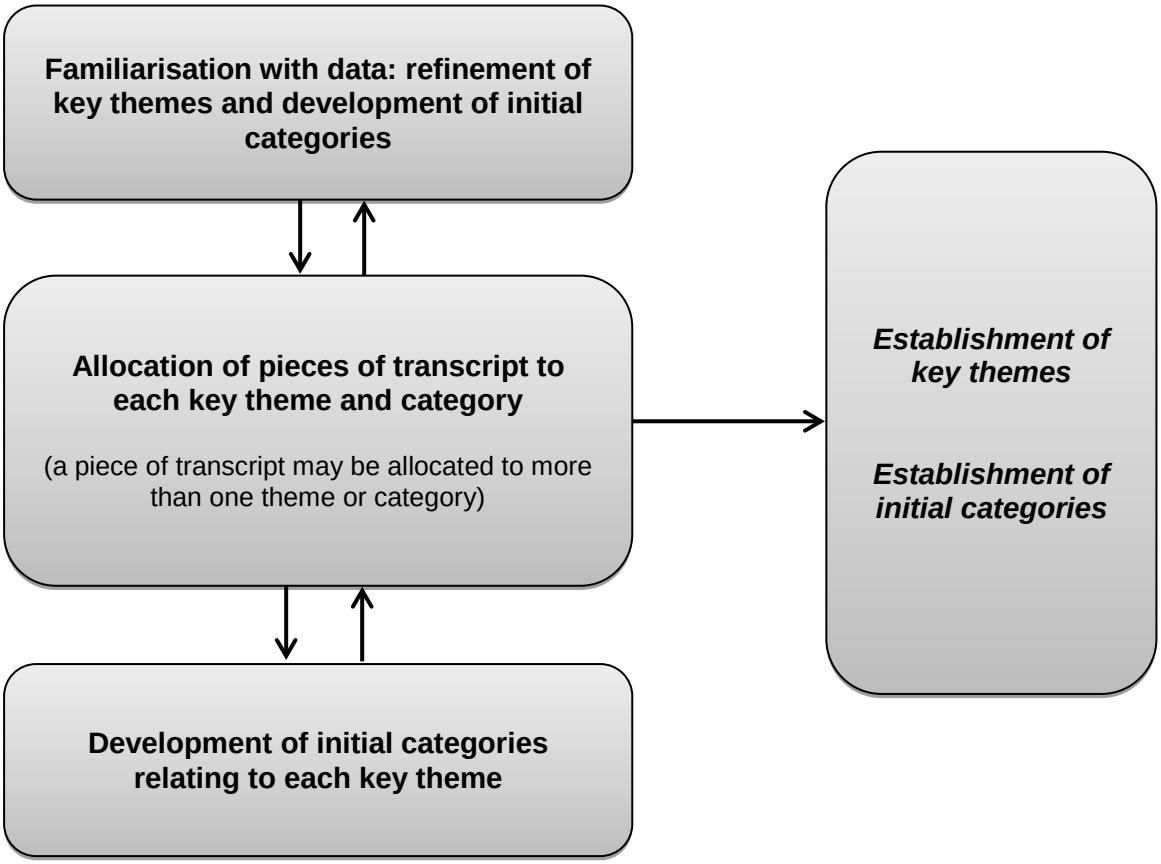
‘Oh we really have to get her in…’</td><td>The midwife doesn’t regard RAADP as a priority. Not an important intervention – is this because it is not of particular benefit?
Implication is that they would not rush to follow up care to ensure a woman receives her anti-D Ig.
Is it difficult to arrange for the woman to attend?
No mention of involving the woman in this process.</td><td>• Perception of benefits of anti-D Ig
• Importance/significance of RAADP
• Midwives’ sense of responsibility in relation to anti-D Ig
• Involving women in their care
• Ways that care is organised</td><td rowspan="3">• Midwives perceptions of the benefits of anti-D Ig
• Sources of information and education in relation to anti-D Ig
• Midwives’ responsibility and accountability in relation to anti-D Ig
• Informed decision making in relation to anti-D Ig
• Midwives and policy in practice</td></tr>
<tr><td>We were here the years...</td><td>The midwives remember when RAADP was not offered. Implication is that the women didn’t used to receive it so is it that important?</td><td>• Importance of RAADP
• Midwives’ personal experience of RAADP</td></tr>
<tr><td>Unless they had a bleed</td><td>The midwives would act differently if a woman had a PSE. This is seen as important and something to invoke action.</td><td>• Importance significance of anti-D Ig following PSE
• Midwives’ sense of professional responsibility in relation to anti-D Ig</td></tr>
<tr><td colspan="4">Preliminary Thoughts: The first thoughts and ideas that the researcher had when reading the text.
Initial Categories: Represent similar themes and concepts derived from similar sections of transcript
Key Themes: The important themes within the data, some of which were pre-determined by the researcher</td></tr>
</table>

{It should be noted that the tables in this section are used to aid explanation of the method of data analysis, rather than to illustrate findings. The findings are presented and discussed in detail in Section 7.6}

In the example above (Table 14) some pieces of transcript were allocated to more than one key theme and/or category, this was common to many pieces of transcript. The categories were colour coded and linked to every key theme to which they related, sometimes more than one. The process was repeated for all sections of transcript that had been identified as belonging to a particular key theme. The process was also repeated across all of the key themes using all pieces of transcript that had been allocated to that theme. The researcher did not have another person who was able to look, in depth, at the data. Repetition of the process of allocation of categories, from different starting points, was an attempt to ensure that no passages of text, and/or categories, relating to each key theme were missed.

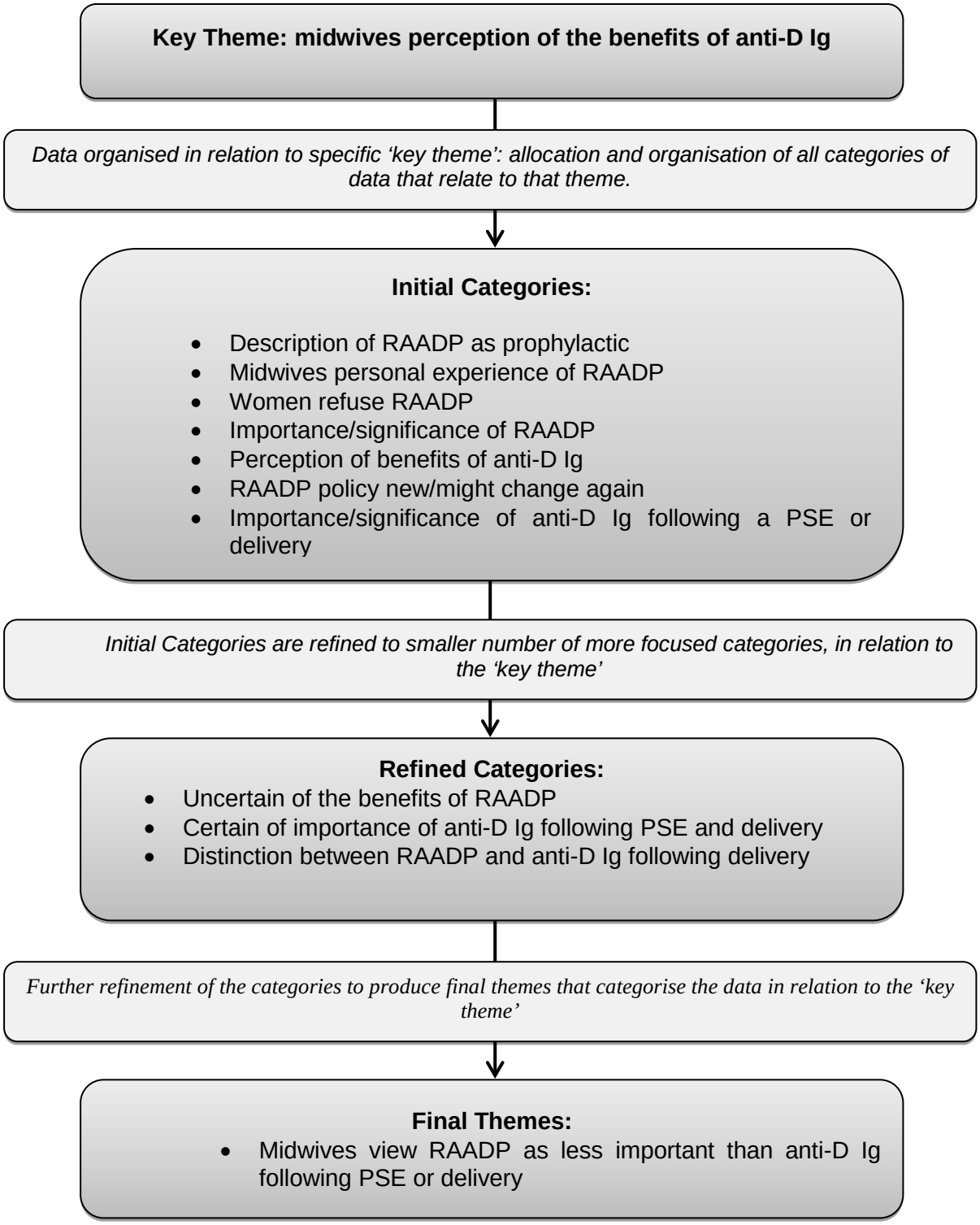
In reality the processes within this first stage of the data analysis were fluid and the researcher moved back and forth between them, with the key themes evolving and being refined as the categories were developed and vice versa. The data analysis process up to this point is illustrated in Figure 11 (below).

Figure 11: Illustration of the process of data analysis



The next stage of the data analysis was to make sense of the categories of data within the key themes, leading to establishment of the final themes. This process involved indexing sections of text according to category and key theme. The researcher also created a chart for each key theme in which categories and final themes were placed in context of that particular key theme. Figure 12 (below), illustrates this process for the key theme 'Midwives' perceptions of the benefits of anti-D Ig'.

Figure 12: Illustration of development of a 'Key Theme'



The final aspect of this research was to make sense of the categories and themes in context of the situations within which they emerged. In doing this the researcher was also able to identify core concepts, that is underlying ideas or concepts that underpin the research and allow the findings to be placed into a wider context. This mapping and interpretation of the findings was completed through creation of descriptive accounts, and it involved referring back to the original transcripts, the indexing and the categories and charts that were created. This was done within the context of the key themes, which represented the important questions that were central to the research aims, and also within the context of the core concepts.

7.6 Findings and discussion

7.6.1 Description of study sample

The midwives were asked to complete a short questionnaire at the end of the sessions. The questionnaire had four questions:

1. Since 2000, for how many years have you worked as a qualified midwife?
   A: 1yr, 2yrs, 3yrs, 4yrs, 5yrs, 6yrs, 7yrs, 8yrs, 9yrs, 10yrs
2. During the past 6 months, approximately how many times have you, yourself, given and anti-D injection?
   A: None or ☐ times
3. Have you ever been directly involved in an anti-D incident?
   A: yes or no
4. Is there anything else you would like to add about any of the issues raised during the focus group, or about anti-D in general?
   A: Free text

There were eleven midwives and the findings are presented in Table 15 (below)

Table 15: Findings of midwives' questionnaire

	Group A N=7			Group B N=4	
Since 2000, for how many years have you worked as a qualified midwife?	7yrs n=1		10yrs n=6	9yrs n=1	10yrs n=3
During the past 6 months, approximately how many times have you, yourself, given anti-D?	None n=2	1-10 times n=3	10+ Times n=2	None n=3	'Lots' n=1
Have you ever been directly involved in an anti-D incident/error?	Yes n=1		No n=6	Yes n=0	No n=4

There were no 'free text' comments from any of the midwives.

7.6.1.1 Group 1: Maternity Unit A

There were seven midwives in the session held at maternity unit A. They were all very experienced, most having spent over ten years working as a midwife since 2000. They had all completed their initial professional training prior to the introduction of RAADP. Two of the seven had not administered anti-D Ig within the past 6 months, 3 had administered it infrequently (less than once a month) and the remaining two regularly administered anti-D Ig. This may be explained by the mix in areas that the midwives were currently practicing in, they were from labour ward, where it would be unusual to administer anti-D Ig, although the midwives there would be expected to take cord and maternal blood samples for the RhD programme at delivery and subsequently explain to women the rationale for doing so and that the outcome might be that they require anti-D Ig. Rarely the same midwives might be expected to

administer anti-D Ig should a woman be discharged home early from labour ward following delivery, as the blood test results would most often delay administration. There were also community midwives present. In this maternity unit those midwives would be expected to discuss RAADP with pregnant women and offer and administer it at 28 weeks gestation. They might also occasionally administer postnatal anti-D Ig to women who were discharged from hospital prior to the baby's blood group being established through cord blood testing. In addition these midwives might also be a first point of contact for women who experience potentially sensitising events such as vaginal bleeding, deciding on appropriate advice and onwards referral for testing and anti-D Ig. The final group of midwives in attendance at the focus groups were midwives working in the day assessment unit. In this area they look after women with a problem relating to pregnancy on an out-patient basis. This would include women who attend hospital following a potentially sensitising event such as vaginal bleeding, and the midwives would assess these women, refer them to medical staff and administer anti-D Ig if it was prescribed by medical staff.

This group was therefore fairly diverse in terms of the current area of practice of the midwives, although all would be involved in the process in some way, they were often dealing with different aspects of the process and different circumstances in which anti-D Ig might be required. Only one of the midwives had been directly involved in an anti-D Ig incident.

In this group the midwives appeared comfortable in each other's company and there were no over powering influences or obviously negative influences on the group dynamic. The midwifery manager gave permission for them to be away from their clinical commitments for one hour, giving around 45 minutes for the focus group session and 15 minutes for an anti-D Ig educational update.

7.6.1.2 Group 2: Maternity Unit B

At maternity unit B, on the day that the session was held only four midwives were able to leave their clinical areas to attend. It became apparent early on that delivery of care at this maternity unit differed significantly from those in other areas as all

RAADP was administered at a special clinic held in the hospital building. This was a change from practice common in other areas where RAADP is given during a routine antenatal appointment at 28weeks by the community midwife.

Again the midwives attending the session were all very experienced, with all of them having trained prior to introduction of RAADP. In this group it transpired that only one of the midwives had administered anti-D Ig within the past six months, this midwife worked in the hospital antenatal clinic and administered RAADP there. The other midwives all worked in the community and because of the set-up of care, with the RAADP clinic, they did not administer any anti-D Ig antenatally. They did however have responsibility for discussing RAADP with the women, referring them to the clinic, and following them up if they did not attend for RAADP.

The fact that one of the midwives in the group regularly administered anti-D Ig and worked in a specialist environment undoubtedly affected the dynamics of this session. It was clear that the other midwives deferred to the clinic midwife and allowed her to answer many of the questions as the perceived expert among them. They also turned to her for clarification if they made points or described policy and practice. This limited the information and quality of data from this session.

For the purpose of reporting findings the quotes from midwives are identified as belonging to either group A or group B, with individual midwives given numbers. For example midwife 1 from group A is (MW1a) and midwife 1 from group B is (MW1b).

7.6.2 Focus group findings: key themes

The first phase of the data analysis resulted in formation of key themes and categories. The initial presentation of findings is superficial, with very straight forward description of the key themes and the categories that were present within the data relating to those themes. This is followed by descriptive account of the findings offering a much more in-depth exploration of what the findings mean in context of the core underpinning concepts. Discussion of how the focus group findings relate to

the research completed in chapters five and six and to the wider evidence base is presented in Chapter 8: Discussion.

The structured nature of the focus groups and the use of the topic guide, meant that some of the key themes reflected the research questions and topics that had been determined prior to conducting the focus groups. However it is of note that during the first phase of data analysis, familiarisation, the 'pre-determined' themes were refined and other new key themes emerged.

Seven key themes were identified

1. Sources of information and education in relation to anti-D Ig
2. Midwives' perception of the benefits of anti-D Ig
3. Midwives' perceptions of the risks of anti-D Ig
4. Recognition and reporting of anti-D Ig incidents
5. Midwives and responsibility and accountability in relation to anti-D Ig
6. Midwives practice
7. Informed decision making in relation to anti-D Ig

7.6.2.1 Sources of information and education in relation to anti-D Ig

The focus group topic guide included questions about formal sources of education and training in relation to anti-D Ig. In addition, during the familiarisation phase of the data analysis, it became apparent that the midwives also sought information from less formal sources. As a result this theme emerged to take into account both formal sources of training and of informal sources of information. After refinement of initial categories relating to this key theme, there were three final themes: training and information is policy focused; the midwives were happy with the learning they received and the midwives access informal sources of information

The midwives' in both focus groups described receiving training around the time of introduction of RAADP. The training was described by them as being focussed on the changes to policy in light of the introduction of RAADP and the midwives

recounted being provided with little information outside of policy changes. In one focus group, a midwife who worked in an RAADP clinic did describe being given some explanation of the rationale for RAADP:

> "They said that some of them had been missed and not known that they'd had a bleed. They said they'd looked at research and brought it out"
> **MW1b**

Her description was very superficial, and at the time the moderator did not explore further whether her understanding was greater than it appeared from this small piece of conversation.

The midwives recalled the training as being provided during face to face sessions, although midwives in both groups mentioned that some of them had been unable to attend. Other means of dissemination of policy changes were described and these included passing on information at team meetings and by pinning a letter outlining the changes to a board in staff areas.

In general the midwives were happy with the level and content of the training that they received. Although there was one midwife in one group who felt that she would like to know more. She was challenged by the other midwives in the group who seemed happy with the frequency and level of training that they received.

The training provided around the time that the policy for RAADP had been introduced was the most recent received by both groups. The midwives, in general, did not see any reason for more frequent updates. They mostly felt that they would only want to have further training if there were significant changes to policy in this area of practice. The midwives also indicated that they felt confident in their own knowledge in this area. They did not identify a need to improve their knowledge or understanding of anti-D Ig, out with being familiar with policy and procedures.

In addition to formal training and dissemination of policy changes, the midwives frequently described seeking advice and information from other sources. They

referred to using product and patient information sheets, and also spoke about calling the blood transfusion service (BTS) laboratory, and also identified specific members of midwifery or medical staff who they would contact.

The BTS laboratory was the most frequently mentioned source of information and advice for the midwives. They not only called to confirm blood test results, but also described a number of situations where they called the laboratory to seek clinical and policy advice concerning particular women. The midwives appeared to have a strong level of trust in the advice that the BTS laboratory gave:

> "Because things are changing all the time, you don't know if somebody's amount of knowledge they've got or whatever. So I tend to phone the lab and say 'this is what I've got, what do you think?' You know because they're dealing with it all the time whereas our consultants, there's a couple I would ask, but the majority I'd phone {BTS}."
>
> **MW1b**

The relationship the midwives described with BTS contrasted significantly with that with their medical colleagues. The midwives in both groups stated that they did not generally turn to medical staff for advice regarding the use of anti-D Ig. The exception to this were specific individual consultant obstetricians who were considered experts in this aspect of care. In fact there were also times when they reported challenging doctors who they felt were not fully cognisant of policy. Midwives in both groups described using BTS laboratories to 'back them up' when they felt the need to challenge medical colleagues.

7.6.2.2 Midwives' perceptions of the benefits of anti-D Ig

It was considered important to explore what the midwives knew and understood about anti-D Ig and, in particular, its clinical benefits and potential risks. This is important in terms of midwives understanding their practice and actions in relation to the care of RhD negative women, and also in order to facilitate informed decision making. This key theme of 'Midwives' perceptions of the benefits of anti-D Ig' emerged following the exploration of the issues, facilitated by the focus group topic

guide. It is followed in the next section by another theme ‘Midwives’ perceptions of the risks of anti-D Ig’.

The very strong final theme within this key theme, was that the midwives who participated viewed anti-D Ig given as routine antenatal anti-D prophylaxis (RAADP) as less clinically significant than anti-D Ig given following a potentially sensitising event (PSE) during pregnancy. This finding was based on refinement of the initial categories to two refined categories: uncertainty over benefits of RAADP and certainty about importance of anti-D Ig following a potentially sensitising event after delivery.

None of the midwives were able to articulate what they thought the clinical benefits of anti-D Ig were for a woman. This was particularly true of RAADP. They all referred to RAADP as ‘prophylactic’, and used the term to distinguish RAADP from anti-D Ig given following delivery or a PSE. In fact all anti-D Ig is given prophylactically in an attempt to prevent maternal sensitisation. The term prophylactic is usually understood to describe prevention rather than treatment, and the midwives appeared to regard the routine antenatal dose of anti-D Ig as preventing something that may or may not happen, in contrast to anti-D Ig given following a PSE or delivery as ‘treating’ an actual event.

All of the midwives who participated had practiced prior to the introduction RAADP and they frequently referred to a time when they did not offer RAADP. This was done in a manner that seemed to question the importance of the intervention and was often done in relation to questions about risk and benefit. The fact that some women decline RAADP was regularly mentioned in the same context. This may be partly explained by the fact that that sensitisation is a very rare outcome and it is unlikely that the midwives would have had direct experience of any clinical benefit following the introduction of RAADP.

A typical extract of conversation was:

"Is there a risk to the woman in not having it {RAADP}?"
Moderator

"Well for years we didn't give it prophylactically."
MW6a

"And women are refusing it, and when they deliver we do check and if they require it again"
MW2a

Although the midwives appeared unsure of the benefits of RAADP, they seemed clearer that anti-D Ig following a PSE such as 'a bleed' during pregnancy was important and significant. They made a clear distinction between the benefits of anti-D Ig in this situation from RAADP.

An example of this was:

"{the benefits to the woman of receiving anti-D Ig} Depends on whether or not she had any bleeding. A number of years ago we didn't do the prophylactic anti-D"
MW1a

And:

"So it {RAADP} isn't one of the big important things that you'd really think 'oh we have to get her in its desperately important'. We were here the years when they never got it before."
MW3b

"Yes, that's right."
MW1b

"Unless they had a bleed"
MW3b

7.6.2.3 Midwives' perceptions of the risks of anti-D Ig

It was also important to consider how the midwives regarded the risks of anti-D Ig. Again their understanding of this issue has important implications for the way they practice and also for any discussion they might have with women who are offered anti-D Ig. This was a topic of interest to the researcher and had been included in the focus groups topic guide. The one final theme, refined from initial categories, was that midwives viewed anti-D Ig as having low risk. A refined category was that midwives' viewed the risk of anaphylaxis as small but significant.

When asked about the potential risks of anti-D Ig, the midwives in both groups mentioned anaphylaxis and they regarded this as the most significant potential risk of the product. The midwives described clinical procedures and practices that were taken in precaution of anaphylaxis. These included carrying ephedrine, and asking the women to wait at the hospital or clinic for 20 minutes after administration of anti-D Ig.

The midwives tone when discussing risk, and in particular anaphylaxis, was very relaxed. Although they described taking precautions and were prepared to treat anaphylaxis should it occur, they did not appear to consider it a very likely outcome.

An excerpt of conversation:

"There's minimal risk in receiving it {anti-D Ig}. I've never seen anyone react to it."

MW5a

"No, no"

Others

"But we take our ephedrine just in case! (laughing)"

MW5a

"That's right! Laughter"

Others

Another refined category was lack of clarity on the risk associated with anti-D Ig being a blood product. The midwives had earlier mentioned unprompted that anti-D Ig was a blood product, and it appeared that most, if not all, were aware of this. However when discussing the risks of anti-D Ig, the midwives did not mention that it was a blood product and the moderator had to ask them directly about those risks:

"What are the risks in relation to it being a blood product?"
Moderator

SILENCE

"Is it something you discuss with the women?"
Moderator

"We tend not to really"
MW3

Although they appeared aware that it was a blood product, they were not at all clear what that meant for a recipient in terms of risk.

"I mean I used to say that it's screened like any other blood but there is that small risk. I would imagine? It is a blood product"
MW2b

The midwives' clearly regarded anaphylaxis as the most significant risk of anti-D Ig, and did not appear to have much understanding at all about any risks associated with it being a blood product. In general they did not appear to consider it a particularly risky product, and reported that they did not usually discuss risks associated with anti-D Ig with women. This is explored further under the broad theme 'Informed decision making'.

7.6.2.4 Informed Decision Making

This was a very important theme to emerge during the data analysis. Although this was an area identified as of interest to the researcher through literature and previous work, it was not something that the midwives were asked about directly during the focus group sessions. The researcher had felt that the topic was too large in itself to explore adequately during a session with limited time and a number of other important issues to cover. However the midwives did discuss this aspect of care, both directly and indirectly, and it emerged as a key theme. There were three final themes associated with this key theme. These were: the use of written information; limited discussion of risks of anti-D Ig; midwives' lack confidence to facilitate informed decision making around anti-D Ig

The midwives mentioned the use of written information a number of times during both focus group sessions, specifically product information sheets and patient information leaflets. They described using these to provide information for women and as a source of information for themselves when they were unsure of something.

It was reported that women were given a leaflet about anti-D Ig towards the start of their pregnancy and midwives mentioned discussing and answering questions in relation to the process of consent for RAADP. It was not clear what form that discussion took, but when questioned, midwives in both groups admitted that it did not include discussion of the risks of anti-D Ig. The midwives stated that they felt that the information provided to the women focussed on the benefits, or reasons for accepting anti-D Ig, and did not cover the risks associated with it.

It seemed that the midwives were not generally confident talking about the risks of anti-D Ig, and that they relied heavily on written information:

"And do they ask you a lot of questions about it?"
Moderator

"Yes, sometimes"
MW4b

"And do you feel able to answer those questions?"
Moderator

"We just relay what's on the information sheets that we give them."
MW4b

The midwives did not appear to be confident in discussing the risks of anti-D Ig, in particular the risks associated with it being a blood product: It was unclear whether or not the midwives routinely informed women that anti-D Ig is a blood product. Although one of the midwives stated that she mentioned to the women that anti-D Ig is a blood product, the same midwife during a different conversation implied that she thought that women did not generally realise that it was

The process of providing written information and receiving formal, written, consent seemed well established when offering RAADP. In particular documentation of refusal of consent was considered important. However consent and discussion were not mentioned at all in relation to anti-D Ig following a PSE or delivery. There was some evidence that the midwives expected that anti-D Ig had been discussed during pregnancy and did not expect to discuss it again if further anti-D Ig was required. For example, a labour ward midwife assumed that the midwives who provide antenatal care would already have discussed anti-D Ig with the women:

"We tend not to really {discuss anti-D Ig with women}. By the time they get to us on labour ward they've had all the stuff and they know pretty much, and they require it. {To another midwife} You are probably dealing with it more than we are?"
MW1a

This midwife also states that anti-D Ig following delivery is ‘required’, the implication being that there is not a decision to be made, unlike for RAADP.

There were a few miscellaneous observations about the way that midwives talked about their discussion with women, including that they described conveying the need for anti-D Ig as it was policy, rather than explaining the benefits or reasons for giving it to the women. The midwives also stated that the women did not really ask many questions about anti-D Ig, and interestingly they always referred to ‘giving anti-D’ rather than ‘offering anti-D’. However, it is difficult to know how significant the use of one phrase or the other might be.

The midwives in one of the focus groups also talked about testing a woman’s partner’s blood type. This started as a very light hearted conversation, but the midwives became more serious and conveyed that they felt there was value in having the baby’s father tested. However, they did not appear to view it as their responsibility to either offer the test or to arrange a test if it was requested. They firmly placed responsibility for this with the parents.

7.6.2.5 Midwives’ responsibility and accountability in relation to anti-D Ig

The midwives’ responsibility and accountability was apparent in almost every aspect of their conversations during the focus groups, and became a ‘core concept’ of the findings. The more specific nature of the midwives’ understanding and application of responsibility and accountability also emerged as a key theme. This was a topic that had also been identified as important from previous research presented in Chapters five and six, and from literature.

The complexity of the inter-related responsibilities was extensive. To aid understanding of the findings the description of initial categories and themes that was mapped during data analysis is illustrated in Table 16 (below).

Table 16: Midwives' responsibility and accountability, initial categories and themes

Initial Theme Midwives' responsibility and accountability in relation to anti-D Ig		
Initial Categories	**Refined Categories**	**Final Themes**
• Clear about their responsibility and accountability when administering anti-D Ig • Clear on their responsibility for following policy/protocol • Responsibility to report errors is clear and well understood • Strong sense of professional responsibility	• Clarity of professional responsibility in relation to policy	• System impacts on who is responsible and ability to practice responsibly
• Lack of clarity over who is responsible when care is shared/transferred • Sense of accountability if care is not given according to policy • Relate anti-D Ig error to that of a drug/medicine error	• Clarity of responsibility in relation to reporting errors	• Midwives have a strong sense of own professional responsibility in relation to policy
• Documentation of care and conversations is regarded as important aspect of responsibility • Documentation can be used to end/transfer responsibility • System can impact ability to follow policy	• Documentation used to convey or establish responsibility	
• Midwives would like women to take more responsibility for their own care • Delegation of responsibility to other midwives and medical staff • Seek advice from trusted sources when uncertain • Do not always trust knowledge/practice of colleagues to whom they delegate care • Frustration when have to delegate to untrusted colleagues	• Conflict over sharing responsibility with women	• Lack of clarity when delegation/sharing of care
• Happy to delegate to trusted colleagues	• Delegation of responsibility	
Core Concepts Responsibility Knowledge and understanding Organisational influence		

On some aspects of practice the midwives were very clear about their professional responsibility. For example when administering an injection of anti-D Ig there was

no doubt in the midwives' minds that they would be held accountable if an error were made:

> "At the end of the day you're giving it so you are accountable for it."
> **MW1b**

This was closely linked to their sense of responsibility and accountability to follow policy and procedures. There were a number of separate occasions when they equated an anti-D Ig error with a drug error.

Documentation also emerged as an important aspect of the midwives responsibility. This included documenting consent for anti-D Ig, checking blood test results and signing prescriptions. Signing for something, putting 'it on the board', or writing things down, were all described by the midwives as ways of ending her individual responsibility in relation to a particular woman's care, or this aspect of her care. This was not a direct hand-over of care and relied on an assumption that the person taking over responsibility would look for, find and act upon whatever had been written.

It was also apparent, however, that in some situations there was lack of clarity over who was responsible for care. This appeared to be happen most frequently when women transferred between clinical areas, or between maternity units. Lack of clarity during handover of care also appeared to be related to procedures, or lack of procedures and to the documentation used.

In both focus groups the midwives described a system of care where they shared responsibility for a woman's care in relation to being RhD negative and administration of anti-D Ig. This was often with other midwives who worked in different clinical areas, and with medical staff who assumed responsibility for certain aspects of care.

In this situation the midwives described having colleagues who they trusted and who they were happy to delegate responsibility to. However they also described situations where it was clear that they were not completely comfortable in handing over care. When discussing referring women to hospital based midwives following a potentially sensitising event (PSE) during pregnancy, for example, they expressed doubt about their midwifery colleague's knowledge of policy. However they did not report taking any further action in that instance. When the same situation arose but it was medical staff to whom the midwives were to delegate responsibility for care, the midwives appeared to extend their responsibility to ensuring that the women did receive appropriate care. They did this through challenging the doctors, sometimes involving other colleagues such as the BTS laboratory to back them up.

> "…because some of the doctors don't agree with it at every bleed. That's when you've got to involve blood transfusion and they insist on it at every bleed."
>
> **MW6a**

The midwives in one of the groups did not prescribe anti-D Ig as, in that particular maternity unit, this was the responsibility of medical staff. However they described an informal shared responsibility with the midwives telling the medical staff what to prescribe for whom.

Another important theme to emerge during both focus groups was the midwives' conflict over delegation of responsibility to women. The midwives expressed frustration that women did not always make themselves available for appointments at around 28 weeks gestation, when RAADP was due to be given. The midwives called for women to share some of the responsibility, but also understood that they would be held accountable if the woman did not receive her anti-D Ig:

”But on the other half when you’ve got this kind of situation, we are told that we are responsible to see that they get their care as well. It’s a difficult line to walk.”

MW2b

“Yes, it is really because if she doesn’t get it and there’s a problem and leads to isoimmunisation they’re going to say ‘well why didn’t you follow her up?’”

MW4b

It was apparent throughout the focus group findings that the midwives’ responsibility and accountability in relation to RhD negative pregnant women was impacted by the organisation within which they worked. This was due to policy, procedures and the organisation of care. The findings relating to this are presented in the following section 7.6.2.6 Midwives’ practice.

7.6.2.6 Midwives’ practice

It became apparent during the familiarisation phase of data analysis that there were a number of factors that influenced midwives’ practice in relation to anti-D Ig, and that policy and procedures often impacted on delivery of care.

Although the midwives were familiar with policy and procedures in their own clinical area, for example the antenatal clinic, labour ward or community, they were often not at all clear on procedures relating to anti-D Ig in other clinical areas. This might not seem important in terms of delivering care, and one of the midwives acknowledged that were she to go and work in another area she would make sure she was familiar with policy relating to that clinical area. However, it became apparent that the process of deciding that anti-D Ig was required, prescription and subsequent administration relied on actions and procedures in different areas, and that these were interdependent.

There were also instances where the midwives felt that they had to follow policy and procedures, even if this inconvenienced the pregnant woman. The system that they were trying to work within seemed to contribute to their difficulty in providing care:

> "They come up to the GP or {hospital}. If they come up without their notes we'd send them away and they'd make another appointment and get it another time."
>
> **MW2b**

> "If you take their blood at the time, you need the bit of slip to take the, to you know, for their bloods. It's just too complicated if you haven't got the stuff there so it's just not worth doing any of it."
>
> **MW3b**

The midwives also described situations where the women's behaviour or lifestyles impacted on their ability to provide care. This was often tied to unfamiliar patterns of behaviour or documentation, making it much harder for the midwives to provide care in line with established procedures.

The midwives' expressed frustration at times when the system that they worked within impacted on their ability to provide care in line with policy and procedures.

7.6.2.7 Recognition and reporting of incidents

Given the previous research findings, the researcher considered it important to ask the midwives about recognition and reporting of anti-D Ig errors. As a result this also emerged as a key theme within the data. There were two final themes here: recognised errors are likely to be reported to SHOT and recognition of errors may be difficult.

The midwives were asked directly if they had heard of the Serious Hazards of Transfusion (SHOT) report, and most had not. When prompted with an explanation of what SHOT was, some did recognise the organisation, but related it to online

transfusion training and seemed to associate SHOT with blood transfusion rather than anti-D Ig.

Although the midwives were not aware of SHOT's role in relation to anti-D Ig error reporting, they were very familiar with their own local policies for error reporting. These would, through organisational processes, lead to onward reporting of any anti-D Ig errors to SHOT. The midwives were very clear about their responsibility to report errors, and felt strongly that if an error was apparent to them or to their colleagues, that this would definitely be reported. This research was quite limited in this respect as clearly the midwives knew that they should report an error and would be unlikely to state that they would act contrary to this.

The midwives were not asked directly about their experience of anti-D Ig errors, or how they would recognise them, however there were conversations where they highlighted situations where they felt an error could happen, or where they had heard of an error occurring. Midwives in both groups recounted stories about such situations, although from the short questionnaire completed at the end of the session, it was apparent that only one midwife had been directly involved in an anti-D Ig error.

The situations that the midwives described as potentially leading to error all involved care being transferred between clinical areas or maternity units, with difficulties in clarifying who was responsible for administering anti-D Ig and communication issues compounding the situation. The midwives also felt that it would not always be clear from the notes that an error had been made, with documentation also cited as making it difficult to recognise when an error had occurred. These conversations focussed particularly on omission of anti-D Ig.

The broad themes provide the foundation of the findings of this research. However it is also important to consider these themes in context of each other and how this lead to the identification of underpinning core concepts.

7.6.3 Focus group findings: core concepts and descriptive accounts

The final phase of the data analysis was to make sense of the themes that had been identified. This was done through development of descriptive discussion based around the three 'core' underpinning concepts that were identified. This allows for a much more in-depth understanding and of application of meaning to the findings in context of the core concepts and what was already known about the issues.

Core concepts are the underpinning ideas or concepts that add meaning to the findings and allow the researcher to place them into context. There were three core concepts identified:

1. Responsibility
2. Knowledge and understanding
3. Organisational influence

The core concepts were identified during the initial data analysis and, naturally, run through many of the different findings and frequently overlap with each other. The findings here are presented in relation to each of the core concepts, starting with explanation of how each core concept developed. In the following chapter, Chapter eight: discussion, the findings are discussed in relation to the thesis as a whole and in context of relevant evidence.

a) Responsibility

The concept of responsibility was central to the findings. It impacts on almost every aspect of the work and overlaps significantly with the other core concepts. This is not perhaps surprising as responsibility, and accountability, sit at the heart of provision of quality health care: professional and personal responsibility of those providing care and the responsibility of the organisation to adequately support them in its delivery.

There are a number of important factors that influence midwives' responsibility and accountability in relation to anti-D Ig. The literature reviewed in Chapter three found that policy and formal guidance on the care of pregnant women with an RhD negative blood type is formed by medical and scientific staff with little midwifery input. Yet midwives are key providers of care and an important source of information for women. The analysis of SHOT error reports, Chapter six, found failures in care involving midwives were often due to failure to follow policy or guidance, or because assumptions were made that others such as medical or laboratory staff would have carried out appropriate checks. The researcher had identified midwives' responsibility and accountability as one of the predetermined issues for exploration during the focus groups. The topic guide contained a number of scenarios and follow up questions that related to professional responsibility and accountability. These referred to different issues surrounding anti-D Ig including situations where midwives might consider deviating from policy or procedure, and specific clinical scenarios where midwives might be expected to share responsibility with other professionals. In addition the sessions elicited further isolated passages of conversation where the midwives made comments that were considered relevant to this topic. Given this and the wide reaching consequences of responsibility, it is not surprising that it merged as both a key theme within the initial analysis and also as a core concept underpinning the entire findings

b) Knowledge and understanding

The second of the three core concepts was that of the midwives' knowledge and understanding. One of the pre-determined issues for discussion during the focus groups had been midwives' education and training in relation to anti-D Ig. This evolved into the key theme of 'sources of information and education in relation to anti-D Ig'. When considering the initial findings it was clear that midwives' knowledge and understanding impacted on almost every aspect of the conversations during the focus groups. This perhaps should not be surprising as our knowledge and understanding of a subject is bound to influence what we say, feel and how we behave. However establishing it as a core concept allowed the findings to be

explained in context of midwives knowledge and understanding of issues around anti-D Ig.

c) Organisational Factors

The SHOT anti-D Ig error report analysis, Chapter six, and the RAADP Survey, Chapter five, both found that organisational factors impacted significantly on care provided by midwives. However this was not one of the pre-determined issues for exploration during the focus groups and it did not emerge as a key theme during the initial analysis of the conversations. During the later stages of analysis, when considering the focus group analysis in greater depth and applying meaning to the findings, it was clear that organisational factors impacted greatly on many aspects of the findings and it became one of the three core concepts which allowed the findings to be placed into context.

7.6.3.1 Descriptive account of findings

The following descriptive account considers the findings of the focus group research within the context of the three core concepts.

7.6.3.1.1 Midwives' Focus on Policy and Procedure

A significant finding of the focus group research was that the midwives considered following policy and procedures as key to their clinical practice. The three core concepts were integral to understanding and explaining this finding. The midwives described a strong sense of professional responsibility to know, understand and follow the policy and procedures that directly affect care that they provide. It was also apparent that the situations where midwives described a strong understanding of their professional responsibility were those where the consequences of failure to act, or to provide appropriate care, were explicit and easily understood. One example of this is that the midwives regarded getting the process of administration of anti-D Ig right as incredibly important. The conversations that the midwives had about this demonstrated not just a sense of responsibility but also an understanding of their accountability in relation to providing care that was not in line with local policy. The sense of accountability and responsibility in relation to errors in administration of

anti-D Ig was further demonstrated with the midwives likening an anti-D Ig administration error to a drug or medication error. Accountability was clearly important to those who participated, with midwives frequently mentioning fear of being held responsible should an adverse outcome arise.

In the UK midwives have three formal aspects to their accountability: professional; contractual and legal. Their professional accountability relates to their status as a registered midwife and requires them to provide care in line with the standards outlined by the Nursing and Midwifery Council (NMC). Contractual responsibility refers to their responsibility to their employer. This requires them to follow the policy and procedures set out by the organisation within which they work. Legal responsibility requires them to provide care within the legal framework, the most significant aspect being not to do harm to another person.

Contractual accountability means that the organisation within which midwives work will significantly influence the way that they practice through specific policies and protocols that they are expected to adhere. Provision of care will also be impacted by the way that care is organised and through the culture fostered by the organisation and its employees. Woman centred care has been an integral aspect of government level maternity care policy in the UK for several years, and it is recognised that working in partnership with women enables them to make choices about their maternity care that are appropriate to their individual circumstances, achieving better outcomes (DoH, 1993, Maternity Services Action Group, 2011). However, the midwives here described providing care that was centred on local policy and protocol, rather than on the needs of the individual woman. They recounted situations where they felt compelled to follow procedure even if that led to inconvenience for the woman, or might expose the woman to potential failures in care. An example was when midwives described delaying administration of anti-D Ig as they did not have the appropriate paper work in the clinic area. When this happened, women were not given anti-D Ig and were asked to return on another date. This may cause significant inconvenience, requiring re-organising childcare, transport or further time off work, and it may also give the impression that anti-D Ig

is something that can be delayed, lessening the impetus to return specifically to receive it. However the midwives clearly felt bound by their responsibility to follow procedures and the way that care was organised appeared to make it difficult for them to act in any other way in this situation. The midwives in effect described an inability to be flexible in their approach to provision of care because of procedural requirements set by the organisation within which they worked, and due to the way that care was organised and required to be delivered. The core concept of knowledge and understanding was also important when trying to understand this finding. Authors such as Wray (2000) and Wickham (1999b) have suggested that healthcare professional's knowledge in relation to the care of RhD negative pregnant women, and the use of anti-D Ig in particular, is lacking. With some suggesting that poor understanding of the issues involved might influence failures in care. The midwives knowledge and understanding of issues around care provided for RhD negative pregnant women and anti-D Ig was not formally tested during this research. However, it was very apparent from the focus group findings that the midwives' knowledge centred on local policy and procedures, and that they lacked understanding of the wider issues and evidence that underpinned the care they provided.

7.6.3.1.2 Education and Sources of Information

Midwives have a professional responsibility to understand the care that they provide (NMC, 2008). In order to provide safe and effective care they need to know policy and protocols, but they should also understand the rationale for their actions and be able to explain the care that they offer to women. The midwives here were asked about the education that they received and, on the whole, they did not feel a need for further education or training beyond dissemination of policy changes. Failure to acknowledge this responsibility and failure to recognise the significant gap in their knowledge and the impact it might have on the care they provide may simply reflect their poor understanding of the issues, although it was not possible from this research to explore this any greater depth.

The midwives' own responsibility for their professional development is critical, however the organisation that employs them also assumes responsibility to support midwives to provide evidence based practice. The focus groups found that provision of education and training on anti-D Ig and the care of pregnant women with and RhD negative blood type was limited. For both groups it had been over two years since it was last offered, and on that occasion there had been dissemination of changes to policy and procedure with minimal information about the rationale or evidence base behind RAADP. The midwives also reported that not all of them had been able to attend the education sessions offered. Instead they received information on the policy change through colleagues, at meetings and via written correspondence. It appeared that, at an organisational level, there was no requirement for them to attend a session, and the education had been organised and provided in such a way that it had not been possible for them all to do so. It would also seem that the opportunity to provide more in-depth background information and understanding that presented with the introduction of RAADP had not been exploited, further reflecting an apparent culture of dissemination of policy rather than providing education that would impart understanding of underlying issues and evidence. There was an apparent failure at organisational level to recognise a requirement to provide care beyond the basic clinical recommendations outlined in the NICE guidance.

The midwives' description of clinical practice that prioritised adherence to following procedure ahead of provision of woman centred care, illustrates the complex relationship between their professional responsibility, their knowledge and understanding of the issues involved and the influence of the organisation within which they work.

7.6.3.1.3 Woman centred care and informed decision making

The conflict between the midwives responsibility to provide care in line with procedures determined by their organisation and provision of individualised person centred care was also apparent in the relationship that they described having with women in their care. They expressed frustration that the women often failed to attend appointments to receive RAADP, and described this behaviour as 'irresponsible',

stating that women should share responsibility for this aspect of their care. However, women cannot fully share responsibility for their maternity care if they do not have information about the choices available to them and the midwives here did not engage with the women in order to discuss RAADP. Despite their rhetoric, the midwives maintained a strong sense of the need to fulfil their professional responsibility to the women in such cases although this was linked to their understanding that they would be held accountable should there be a subsequent failure in care, as opposed to concern over provision of evidence based care.

Informed decision making is integral to the provision of woman centred care, and is important in relation to anti-D Ig for a number of reasons. The evidence described in Chapter three, highlights the significance of information in empowering women and enhancing the quality of the maternity care that they receive. Additionally, with anti-D Ig, the efficacy of both RAADP and anti-D Ig following PSE is dependent on receiving it at the correct time. In both cases the women must be able to recognise the need for anti-D Ig and attend to receive it. This requires partnership between care givers and the woman in order to impart that information and support provision of appropriate and timeous maternity care.

A number of authors have linked the underlying knowledge and understanding of healthcare professionals to their ability to provide informed decision making (Kirkham, 2004, Oliver et al, 1996). This research uncovered significant limitations in midwives' knowledge and understanding about anti-D Ig, which the midwives' themselves gave as a reason for their failure to fully engage with women in discussion about the intervention. Exploration of the focus group findings about informed decision making in relation to the core concept of midwives knowledge and understanding about anti-D Ig aids understanding of some of the issues raised. In particular the midwives were unclear about the risks and benefits of anti-D Ig, focussing on the immediate clinical consequences of administration, such as the risk of anaphylaxis. Although they clearly took the potential risk of anaphylaxis very seriously, they also described being unwilling, and feeling unable, to engage in discussion with the women about the other risks, even stating that they actively avoid

discussion of this type. The risks and benefits of anti-D Ig are complex and difficult to quantify. This complexity is enhanced by the fact that a woman's individual circumstances impact on them. However they also form an extremely important part of a woman's decision about whether or not to accept anti-D Ig and it is vital that women are offered an opportunity to discuss the risks and benefits of anti-D Ig in relation to their own individual situation if informed choice is to be achieved.

Organisational factors also emerged as an important influence on the provision of informed decision making. The focus on provision of education around policy and procedure, rather than developing a wider understanding of the underpinning evidence base and issues impacting women's decisions, impacts midwives knowledge and subsequent ability to provide informed decision making. However it was also clear from the focus groups that while the midwives recognised that they did not have the knowledge to engage in this depth of conversation with the woman, they did not see a need for this, or regard it as important that they did so. The midwives in the focus groups reported a shared culture of failure to engage in discussion about the risks of anti-D Ig. Instead they described the use of written information to provide women with information about anti-D Ig. They used both patient information sheets and also the product information sheets provided with anti-D Ig. Product information sheets are intended to give details about the product from a pharmacological perspective rather than provide information that might allow a woman to consider whether anti-D Ig is appropriate for her. The midwives here however, reported using them to inform the women and as a source of information for themselves. The focus groups did not explore content of the leaflets used by these midwives although previous research, the RAADP survey described in Chapter five, found that patient information leaflets vary considerably in quality and content. The midwives also stated during the group discussion that the information they provided did not cover the risks of anti-D Ig but rather focussed on the benefits, providing further evidence of a culture of avoiding imparting the risks of anti-D Ig to women.

This research found that the midwives were dependent on written information as a source of information for themselves too, reinforcing their lack of knowledge and

understanding about the information that they were required to impart. This raises questions about the quality of information available to women and health care professionals to aid decisions about care, and the influence that individual maternity units and individual midwives have upon that.

It is also interesting to consider the provision of informed decision making within the context of responsibility. Midwives have a professional responsibility not only to provide women with choices, but also to inform them of potential risks that an intervention might hold. The midwives here centred their responsibility on obtaining written documentation of consent required by local policy, rather than engaging in a process that would allow women to make a decision based on individual circumstances. This may be regarded as prioritising their obligation to their employer to document that procedure has been followed, rather than responsibility to women to provide individualised care.

These findings raise questions about organisational influence on knowledge and understanding and on the cultural context within which care is offered. There may also be organisational factors that directly influence the midwives ability to provide this care, such as time available during appointments, however the midwives here did not mention any such factors as impacting on ability to achieve this.

The midwives' did mention a process of consent in relation to RAADP although, as already discussed, this was centred on documentation of the woman's agreement to receive anti-D Ig. They did not mention consent at all in relation to anti-D Ig given for postnatal prophylaxis or following a PSE in pregnancy. Their conversation implied that these were situations where they regarded anti-D as simply required rather than to be offered, with an assumption that the women had had an opportunity to discuss anti-D Ig during the antenatal period. However, the anti-D Ig is being offered for a different clinical reason and the woman may have different criteria for deciding to accept or decline it. The midwives have a responsibility to discuss it again in the context of the current clinical situation. Without understanding the basis

and underlying evidence relating to the policy the midwives may neither appreciate this, nor be able to do so.

Oliver et al (1996) state that the call for more choice in maternity care has not been accompanied by corresponding investment in training professionals or organising health care to make time available for this. This reflects the concerns of the Royal College of Midwives when RAADP policy was first proposed (RCM, 1999) and raises questions about the extent to which the recommendation from NICE that implementation of a policy of RAADP should be accompanied by staff training (NICE, 2002) has been achieved. The survey conducted in Chapter five found that the majority of maternity units did in fact accompany introduction of a policy of RAADP with staff training or education. However the findings in this chapter raise the question of whether that was at a level that would allow meaningful engagement with women about the risks, benefits and alternatives associated with anti-D Ig.

Provision of informed decision making is an important aspect of care provided to pregnant women with an RhD negative blood type. Midwives ability, and willingness, to facilitate this is influenced by the organisation that they work within, their knowledge and understanding of the issues involved and by their own interpretation of their responsibilities to women and of the responsibility required of them by their organisation.

7.6.3.1.4 Midwives interaction with other healthcare professionals

This research also gave insight to midwives' relationship with other healthcare professionals with whom they shared aspects of care provided for women with an RhD negative blood type. In particular the midwives described having an important relationship with the blood transfusion service (BTS) laboratory staff, frequently relying on the laboratory staff to provide clinical advice concerning the women in their care.

The midwives were happy with this arrangement and they did not seem to consider that it conflicted with their responsibility to know and understand significant aspects

of the care that they carried out. It is of note that it is not always clear who the person they speak to in the laboratory will be. In some instances it may be a medical laboratory assistant (MLA), a person who is unqualified and trained only to provide assistance within the laboratory setting, other times it could be that a registered biomedical scientist (BMS) would answer the phone. BMS's should be very familiar with policy and procedures in relation to testing and issuing of anti-D Ig, however they are not expected to understand and advise on specific clinical situations. If midwives are relying on laboratory sources for clinical advice it is important that they understand the limitations of any advice they receive, and must also be aware that they remain responsible for any action they take as a result. This research didn't explore this further but it is an area of the midwives' practice, and their understanding of responsibility linked to that practice, which warrants further exploration.

The findings here describe a culture where the midwives were happy to access clinical advice this way and that the laboratory staff appeared to be available and willing to provide it. The findings of this research suggest that the midwives here regularly accessed information to inform their practice from informal sources such as BTS staff and from product information inserts that were not intended for that purpose. This would suggest that they did not have access to, or know how to access, more formal and reliable sources of information. The organisation within which midwives work has an obligation to ensure that they have access to such sources of information.

This was not the only situation where other healthcare professionals practice impacted on the care that midwives provided. The way that maternity care is organised means that administration of anti-D Ig is often part of a process involving other healthcare professionals. For example medical staff might make a decision to give a certain dose of anti-D Ig to a particular woman and then write the prescription, the laboratory staff will often select the correct product and dose and issue it to the clinical area, with the midwife administering it to the woman. The responsibilities of individual professions will vary between maternity units according to local policies

and procedures. Although the person who administers the anti-D Ig is ultimately responsible for their action, the degree to which there is shared responsibility across the process is complex and medical and laboratory staff may also be held accountable for their actions. Analysis of SHOT error reports, described in Chapter Six, identified a number of situations where the lines of responsibility and accountability were not clearly defined. In particular when medical colleagues erroneously prescribed anti-D Ig or where laboratory staff issued the wrong dose to the clinical area and a midwife offered and administered it. However, the focus group research found that the midwives were clear in understanding that they were responsible, and would be held accountable, if they administered anti-D Ig as part of a process where others were involved.

When sharing care with other professionals, the research uncovered situations where the midwives described extending their professional responsibility to take on personal responsibility for a woman's care. Personal responsibility reflects a person's own sense of what is right or wrong and how they should behave, with Mander (2004) regarding it as the highest form of accountability that a person holds. An example of the midwives sense of personal responsibility came when they described situations where they felt that medical staff, to whom they were required to delegate care, did not fully understand policy. In such situations the midwives described going beyond their professional responsibility to ensure that the women received what they considered appropriate care. Interestingly this did not extend to midwifery colleagues, instead they described a sense of resignation and frustration at having to hand on care to them, but did not act further to intervene. It is interesting that the midwives perceived a hierarchy of their responsibility where they felt unable to challenge another midwifery colleague but they would challenge a member of medical staff who held a different role within their organisation and had different professional responsibilities. It is of note that the midwives in this research were all very experienced and had been practising as midwives for a number of years. It was not possible to explore here whether their willingness to assume responsibility over colleagues was linked to professions or was influenced by other factors such as

perception of experience or competence of individual clinicians within those professions. This would be another interesting aspect of the research to explore further.

Another example where the midwives' sense of personal responsibility saw them work beyond the policies dictated by their employer was when they discussed paternal blood type testing. They clearly thought that it would be advantageous for women to know their partners blood type, and potentially avoid receiving anti-D Ig, but did not consider it within the scope of their role or responsibility to offer it. Instead they described informally advocating testing by advising the father to donate blood to find out their blood type. Although the midwives intention was sound this unofficial method of testing, without formal reporting of results, may be unreliable and is unlikely to provide a result before the woman's pregnancy reached a stage where RAADP would be offered. The midwives' failure to understand the implications of the advice they gave, again highlights failure to fully understand the wider issues that influence decision making around anti-D Ig. It also demonstrates the difficult situation that midwives are in when they have a responsibility to their employer to provide care in line with policy and guidance but this conflicts with their own sense of personal and professional responsibility to provide evidence based options of care for pregnant women.

Organisational factors also influence the midwives interaction with other health care professionals. The care of a woman during pregnancy will often be shared between clinical areas at different stages of the pregnancy and birth, particularly if the woman requires additional care or intervention due to complications of pregnancy. It was interesting to note that although the midwives felt clear responsibility for the direct care that they provided, they did not regard it as important to know or understand procedures and practice in those other clinical areas. This has potential to impact on care that they themselves provide and is especially challenging in situations where there are not robust systems for handing over care, potentially leading to failures in care. The midwives reported situations where there was a degree of confusion concerning who was responsible for particular aspects of care and also described a

lack of clear procedures for handing over or communicating changes in responsibility. The way that care was organised appeared to impact on this, and they described procedures for handing over care, such as writing a name on a board or ticking a box, that did not require the healthcare professional to whom that care was being delegated to acknowledge receipt. While midwives may have a responsibility to their employing organisation to follow procedures, the organisation equally has a responsibility to ensure that policies and procedures are robust and enable safe and effective clinical practice.

The organisation of maternity care can have a very direct impact on midwives practice, and the focus group research uncovered examples of differences in organisation of maternity care and of policy at the two maternity units where the participants practiced. For example in one maternity unit the midwives prescribed and gave all routine antenatal and postnatal anti-D Ig, but in the other prescription of all anti-D Ig was the responsibility of medical staff, although the midwives offered and administered it. The midwives in the two maternity units clearly had very different roles and responsibilities in relation to administration of anti-D Ig, dictated by the organisation of care and the specific policies in place at their respective employing organisations. In another example one of the maternity units held an RAADP clinic, with all RhD negative women asked to attend the hospital clinic in order to receive their RAADP. As maternity care becomes increasingly complex and specialised there may be a tendency to organise it in a way that sees some aspects delegated to specific professionals. A midwife who worked in this RAADP clinic was a participant in the focus group and during the session it was very clear that she was considered an ‘expert’ and that the other midwives knew very little about procedures relating to anti-D Ig their maternity unit. Although these midwives felt that they did not require this knowledge because all RhD negative pregnant women would attend the RAADP clinic, it also emerged that anti-D Ig remained a significant aspect of their clinical practice. They had responsibility for informing the woman of her blood type, providing initial information concerning the significance of being RhD negative during pregnancy, they would be a first point of contact if she

experienced a potentially sensitising event during pregnancy, and were also responsible for administering anti-D Ig after a homebirth. The way that the system was organised in this hospital appeared to foster a culture among the midwives that it was acceptable to delegate all things anti-D Ig to the hospital midwives. However this failed to take into account other factors, aside from actual administration of anti-D Ig, that require midwives to understand the issues involved. The way that care was organised in this maternity unit made it difficult for midwives outside of the clinic area to remain up to date and aware of policy and procedures even although those policies and procedures impacted on the care that they provided.

7.6.3.1.5 Recognising and reporting anti-D Ig errors

The focus groups also explored reporting of anti-D Ig errors, and although this was done to a very limited extent, it remains useful to attempt to understand the findings in relation to the core concepts. Midwives in both groups described robust systems for reporting anti-D Ig errors and stated that they fully understood those systems. Their professional, and contractual, responsibility in this respect was also well understood with the midwives expressing that they would always report an incident. This could be said to reflect the culture of encouraging openness and accountability when errors happen, however clearly this research was not designed to explore this issue and it is not at all clear how the midwives might have behaved had they actually made an error.

The error reporting systems that the midwives described would lead to onward reporting to the Serious Hazards of Transfusion (SHOT) reporting scheme. However this was largely done through a process that was remote from the clinical midwives. Clinical staff reported any error via their local system, DATIX, and then another person was responsible for investigation and onward reporting to SHOT. It was clear from the focus groups here that the midwives did not understand the function of SHOT in relation to anti-D Ig. Although some of them had heard of the scheme this was in relation to blood transfusion, and they did not associate it with anti-D Ig. The purpose of the SHOT scheme is to allow clinical groups to learn from errors, with lessons learned being used to prevent recurrence. However this research found that

the findings and recommendations from the SHOT report were not disseminated to the key clinical recipients: midwives providing clinical care. The midwives did not associate SHOT with anti-D Ig errors, and clearly in this case the organisation had failed in its aim to inform the staff groups who directly impact care. This would appear to be a lost opportunity for clinical staff to learn from a report that is directly relevant to their clinical practice.

7.6.3.1.6 Routine Antenatal Anti-D Prophylaxis

A very significant finding of this research was that the midwives described RAADP and anti-D Ig given following a PSE or delivery, as having different clinical significance: RAADP being considered less important than anti-D Ig given for other reasons. Again it was possible to better understand this finding by relating it to the three core concepts.

The midwives here did not give any rationale to justify their attitude to RAADP, simply referring to the fact that for years they had not given it. The number of women who need to receive RAADP in order for one to benefit is very small and any benefit would impact a subsequent pregnancy rather than the current one. This means that the midwives are unlikely to encounter a woman who has benefited from RAADP, or to see any change in outcomes during their daily practice. This inability to link RAADP to any perceived change in outcomes could be a factor in the lack of benefit they associated with it. This again highlights the implications of learning around anti-D Ig being concerned with policy and procedure rather than understanding the evidence and wider issues involved.

The midwives also expressed that when administering anti-D Ig following a potentially sensitising event (PSE), or delivery, they perceived a clear link between their responsibility to provide care in line with policy and the consequences for the woman of getting it wrong. With RAADP, although they described ambivalent feelings about the clinical significance of the policy, they still reported a strong sense of responsibility to ensure that women were offered the intervention. In this case however, the midwives' commitment to offer RAADP was linked to understanding

that they would be held accountable for failure to provide care in line with procedure. This again reflects the midwives' strong sense of contractual accountability to their employer.

The focus groups included only a small number of midwives and, importantly, they were all very experienced, and had all practised as midwives before RAADP was introduced. It might be that had a group of midwives who had qualified after introduction of RAADP been interviewed, the findings would have been different. That said the strong sentiments voiced by the Royal College of Midwives (RCM, 1999) around the time that RAADP was recommended together with the findings of this research suggest that this is an area of practice that could be explored further. Midwives' attitudes and subsequent actions in relation to women who receive RAADP has potential to impact on clinical practice, compliance with guidelines, and informed decision making.

7.6.3.2 Summary of descriptive account and core concepts

The focus group research suggests that the midwives have a strong sense of responsibility and of being held accountable, but raises questions about whether they fully understand the scope of their responsibility. Their sense of responsibility was closely linked to their accountability to their employing organisation and the complexity of professional responsibility and of responsibility to the women in their care did not appear to be well understood. This drive to provide care in line with the policy and procedures of their employing organisation impacted their ability to provide care that was flexible and woman centred. The midwives' knowledge and understanding also impacted on the care they provided, and in turn was influenced by the organisation within which they worked. The education that midwives received again centred on knowing policy and procedure. The lack of information provided to them about the evidence base underpinning policy meant that they could not support women in a process of informed decision making and their lack of understanding impacted the clinical care that they provided. Organisational factors were found to directly influence the midwives practice through the way that care was organised and through specific policies and procedures. However the findings also suggest a less

immediately obvious influence through fostering a culture of following policy and procedure rather than providing woman centred care.

The findings illustrate that the core concepts of responsibility, knowledge and understanding, and organisation factors underpin and influence almost every aspect of midwifery practice in relation to provision of care for pregnant women with an RhD negative blood type.

7.7 Strengths and limitations of this research

The strengths and limitations of this research are discussed in Chapter eight, section 8.4, Pg 226.

Chapter 8: Discussion

8.1 Introduction

This research was conducted using three different methods, over a period of five years, with the aim of describing practice and policy surrounding the care of women with an RhD negative blood type from a midwifery perspective. The research found that by 2005 the NICE (2002) recommendation for routine antenatal anti-D prophylaxis (RAADP) had been widely implemented throughout the UK, but that there were significant variations within local policies and the information that was provided to pregnant women and healthcare professionals. The secondary analysis of the SHOT anti-D Ig error reports from 2007/2008 highlights aspects of practice and organisation of care that may result in errors occurring. Identification of proximal errors, trigger events and fallible practices provide valuable information for clinicians about how errors involving anti-D Ig occur. The final research, focus groups to gain a midwifery perspective, found that the midwives and the organisations within which they worked were driven to provide care in line with policy and procedure at the apparent expense of a woman centred approach. This appeared to be linked to the midwives' understanding of their responsibility and accountability and the education and information that underpinned the care they provided. The other important finding from the focus group research was that the midwives regarded RAADP as a less important intervention than they did anti-D Ig given following a potentially sensitising event (PSE) during pregnancy or given following delivery.

The strengths and limitations of the individual research projects were discussed alongside the findings within their specific chapters: Chapters five, six and seven. They are discussed again here within the context of the wider application and validity of specific findings and conclusions drawn. When considered together the research findings give unique and valuable insight to the care of pregnant women with an RhD negative blood type in the UK, from a midwifery perspective. The following

discussion aims to place the findings into context of the research as a whole, of the wider meaning and application of the findings for midwifery practice.

8.2 Building the thesis from three pieces of research

The thesis consists of three distinct, but related pieces of research. It is important to consider how they relate to one another and what each piece contributes to the thesis overall.

The aim of the RAADP survey was to determine actual implementation of what was a new and, at the time, controversial recommendation. The survey formed the foundation on which to build the thesis by providing evidence that RAADP had become an integral aspect of maternity care within the UK. The findings describe policy across the UK but were not able to explain why aspects of implementation varied between maternity units, or what impact those variations might have on clinical practice. This raised important questions that informed the two subsequent pieces of research and also aided explanation of the findings of those research studies.

The RAADP survey raised a number of questions about clinical practice in relation to the recommendation to offer RAADP. The second piece of research was a secondary analysis of anti-D Ig errors reported to the SHOT scheme. This work has arguably the most potential to be directly useful in clinical practice as it highlights aspects of organisation of care, local procedures and clinical practice which create situations or events that allow errors to happen. The findings highlight both individual and organisational impact on errors, and are unique and important as this is the first time that the SHOT anti-D Ig error data has been examined from a midwifery perspective. The research uncovered proximal errors, trigger events and fallible practices which provide a framework within which the common pathways to error involving anti-D Ig can be better understood, allowing midwives to understand and improve the care they provide. This piece of research also raised further questions about midwifery practice and those questions were used to inform the focus group research.

The aim of the focus group research was to consolidate the findings of previous research, presented in Chapters five and six, by gaining direct input from midwives. It met this aim to a large extent, and although the findings are limited by the factors discussed in Chapter seven, this research adds substance to the findings of Chapters five and six, to the wider evidence base and provides foundations for future research. This aspect of the research allowed midwives an opportunity to clarify and explore the issues that had been raised, giving a midwifery perspective, something that had never been sought before. It answered the questions raised through the previous research and allowed exploration of other aspects of care relating to women with an RhD negative blood type.

This research represents the first time that a midwifery perspective on care provided for women with an RhD negative blood type has been explored. When considered alongside each other, the findings of the three pieces of research provide original and important insight to midwifery practice in relation to the care of pregnant and parturient women with an RhD negative blood type.

8.3 Discussion of findings

The findings of all three pieces of research are discussed here, in relation to each other and the available evidence. In order to impose some structure to the discussion sub-headings are used within the discussion of findings. However, the findings are interrelated and it was frequently necessary to revisit particular issues when those were raised in context of further findings or pieces of research, necessitating discussion across subject headings

8.3.1 Anti-D Ig in practice

The research findings shed light on a number of important aspects of midwifery practice in relation to the care of RhD negative pregnant women and the administration of anti-D Ig in particular.

The RAADP survey was conducted in 2005, soon after the NICE (2002) recommendation for RAADP was published and at a time when it was unclear how

many maternity units had actually implemented the recommendation. Previous audit found just 12% of maternity units offered RAADP (Chilcott et al, 2004), but this survey found widespread adoption of the policy with 75% of maternity units offering RAADP. At the time this was a very important finding which demonstrated the impact that the NICE guidance had and the contemporaneous significance of the findings were demonstrated through mention of the survey in the review of the NICE guidance (NICE, 2008, Pg 7 (Appendix 2)) and publication of an article in Transfusion Medicine Journal (Harkness et al, 2008 (Appendix 1)). Implementation is now assumed to be even more widespread. It is known all of Scotland's maternity units now offer RAADP although it is not clear what the implementation rate is in the other UK countries.

The research also found that although a policy for offering RAADP had been broadly implemented, there were significant variations in the local policies put in place by maternity units. These included whether one or two dose regimen for RAADP was used and whether routine paternal testing was offered. The variations in clinical practice are discussed in Chapter five. It is of note here that just 12% of maternity units offered routine paternal blood type testing. By testing a paternal blood sample it is possible to determine those fathers who are also RhD negative, if both mother and father are RhD negative the baby must also be RhD negative and so there is no risk of maternal sensitisation. As such anti-D Ig is not necessary for those women who are certain that the father of their baby is RhD negative, making the test a useful tool when offering informed choice within an individualised and woman centred approach. However, this research found that the test was not offered to the vast majority of women. The reasons most often cited for not offering the test is potential misidentification of the father by the pregnant RhD negative woman (Urbaniak, 1998). This attitude appears paternalistic, in that it dismisses involvement of the woman in her own care. It is important to acknowledge that this policy perspective is grounded in the scientific and medical professions and that the midwives interviewed for the focus group research, Chapter seven, saw value in determining the father's blood type in order to avoid unnecessary anti-D Ig. Discussion of this sensitive

subject may be considered difficult, however midwives regularly engage with women to discuss sensitive issues. It is also routine practice in many maternity units for midwives to seek time with women when their partners are not present in order to discuss issues such as domestic violence. This could also provide an opportunity for confidential discussion with women about whether a paternal blood test would be appropriate. Although the medical and scientific policy makers may consider this a difficult issue to broach it would appear that midwives would not share those concerns to the same extent. Offering routine paternal blood type testing could be a simple, and potentially cost effective, intervention that supports the NHS policy agenda to provide individualised care, and yet none of the policy documents that recommend RAADP have seriously considered it. There is no formal evidence to inform the use of routine paternal blood type testing for partners of pregnant women with an RhD negative blood type and it appears to have been dismissed as an option by the majority of maternity units.

It is of note that although the midwives in the focus groups supported paternal testing, they felt powerless to offer it, instead suggesting that fathers donate blood to determine their blood type. This situation demonstrates the lack of input that midwives and RhD negative women themselves have had in policy in this area and how the dominance of a medical and scientific approach to addressing the problem of maternal sensitisation and subsequent haemolytic disease of the fetus and newborn (HDFN) may result in failure to consider areas of practice that have potential to improve the quality of care that is offered.

This research also considered clinical practice by examining the mistakes that midwives make when administering anti-D Ig, the first time that such research had been undertaken. There is increasing evidence that clinical error is common within the National Health Service (NHS) (National Audit Office, 2005) and a number of patient safety initiatives have been introduced at National policy level. In relation to the care of RhD negative pregnant women there is little published evidence about how errors occur or what might be done to prevent them. The annual SHOT reports identify trends in type of errors, such as omission of anti-D Ig or inappropriate

administration. They also report on ‘stand out’ errors from which lessons may be learned. However the primary purpose of the SHOT organisation is haemovigilance and its focus is primarily on blood transfusion, with members including haematologists, biomedical scientists and transfusion specialist nurses. There is no midwifery involvement in collating and analysing the data, or in making recommendations for practice based on the report findings. Nemeth and Wessell (2010) suggest that around 50% of medication errors reported within the NHS could be prevented if lessons had been learned from previous experience. The research presented in Chapter six examines only anti-D Ig errors that involved midwives, from the perspective of midwives, for the first time and in doing so provides practical understanding of the factors that contribute to errors in this area of practice. It is anticipated that the findings will allow midwives and maternity units to identify situations within their workplaces and organisations that could be scrutinised in order to prevent error from occurring.

The analysis of the SHOT anti-D Ig error reports involving midwives identified just four proximal errors: the final opportunity to prevent an error within that situation. The four proximal errors were: failure to complete checks, failure to follow up care, misinterpretation of results and failure to follow guidance. The proximal errors reflect what Reason (2000) describes as a ‘person approach’ and may result from forgetfulness, carelessness, poor motivation or even recklessness. These are important for midwives to consider within the context of their professional responsibility, however they are factors which all of us may experience at some time, and as a result they may be very difficult to control or influence even at an individual level. The findings of this research can also be interpreted within the framework of Reason’s ‘system approach’ (Reason, 2000) which takes as a premise the fact that human beings are fallible and will always make errors. Within this context the proximal errors are important in aiding understanding of an individual’s role in making an error, however it is the trigger events and the fallible practices which really allow scope for intervention that may reduce future errors. The research identified a number of relatively simple and easily rectified factors that could prevent

errors from recurring. These included factors influenced by culture and organisation and included numerous examples of poor communication and flawed procedures and ways of working. This is particularly significant as the focus group research found that midwives felt compelled to practice in line with the policy and procedures set out by the organisations within which they worked. Their sense of responsibility and accountability was strongly linked to their obligation to their employer and they described situations where they followed policy and procedure even when they had misgivings about the impact on women. This emphasises the potential for error when procedures and policies are flawed, and reinforces the understanding that those factors require effort beyond the influence of individual midwives in order prevent recurrence.

Although the RAADP survey, Chapter five, found that the majority of maternity units had met their obligation to implement the NICE recommendation to offer RAADP, the subsequent pieces of research suggest that there are often factors within subsequent practice that could be improved. Organisations have a responsibility not only to implement National guidance but to do so in a way that establishes ways of working that enable staff to provide safe and effective care. This may be through ensuring that procedures and documentation minimise the risk of error, but also in supporting staff through provision of education and information. The midwives who participated in the focus group interviews were clear in understanding that they would be held accountable should care not be provided in line with policy, but failed to acknowledge a wider professional responsibility to provide evidence based, woman centred care that facilitated choice. This aspect of their practice is discussed further in the following section 8.3.2: Anti-D Ig and woman centred care.

The number of anti-D Ig errors reported to SHOT has risen steadily since reporting began and it is thought that one of the reasons for the increase is the widespread introduction of RAADP with resultant increase in amount of anti-D Ig that is offered. This research found that the majority of errors reported to SHOT did not involve RAADP, suggesting that it is unlikely that implementation of RAADP policy has contributed significantly to the increased number of errors reported to SHOT.

Evidence reviewed in Chapter three suggests that when care provided for RhD negative women is routine and established, such as following delivery of an RhD positive baby, compliance with guidelines is high (Vause, Wray and Bailie, 2000, Howard et al ,1997). The RAADP survey, Chapter five, found that by 2005 RAADP was widely implemented across the UK, making it an established aspect of routine antenatal care in the majority of maternity units for a number of years now. There is also emerging evidence that compliance with RAADP is generally good (McKenzie et al, 2006, Chaffe et al, 2007). This adds weight to the finding that errors involving RAADP may be less common than errors concerning postnatal prophylaxis and anti-D Ig given following a PSE. However, it is also important to consider that omission of RAADP may be under reported. Anti-D Ig used for RAADP is often held as stock in clinical areas, making it out with the normal controls levied by the laboratories, and omission subsequently susceptible to going unrecognised.

It is interesting that the midwives who participated in the focus group interviews described anti-D Ig given as RAADP as less important than anti-D Ig following a PSE. This is not something that has been reported in the published literature previously, but may have important implications for midwifery practice. It was discussed in detail in Chapter seven, but is significant here as it raises the question of whether midwives are as rigorous in offering and administering RAADP as they might be for anti-D Ig given for other reasons. Although the midwives did not appear to see clear benefit in RAADP, they did describe a very strong commitment to ensuring women were offered, and received, it. This appeared to be linked to their strong sense of the importance of offering care in line with policy and, as such, their feelings about RAADP did not appear to influence this aspect of the care that they provided in relation to it. This adds further weight to previous research that suggest that compliance with guidelines for offering and administering RAADP is good (McKenzie et al, 2006, Chaffe et al, 2007).

The finding that midwives regard RAADP as less clinically important than other anti-D Ig is potentially very significant. However it is important to acknowledge the limitations of this research and to consider whether this finding reflects how

midwives in general feel about RAADP, or if it simply reflects the views of those midwives who participated in this research. It is of particular note that all of the midwives who participated in the focus groups had practised as midwives prior to RAADP being offered and that this may have influenced their view of the intervention. Further research is required to establish whether this is a more general view held by midwives, and to establish the true incidence of error related to anti-D Ig given as RAADP.

A more plausible explanation for the increase in anti-D Ig error reports is increased awareness of the need to report errors and improved systems for doing so. This reflects a wider NHS policy focus on the patient safety agenda, with accompanying widespread implementation of local level formal incident and error reporting systems, such as DATIX, which enable onward reporting to appropriate organisations such as SHOT (National Audit Office, 2005). The focus group research findings support evidence that staff understand how to report errors and that the mechanisms are in place to facilitate onward reporting to SHOT.

It is important to note that although the numbers of anti-D Ig errors reported to SHOT continue to rise, from just 5 in 1998/9 to 249 in 2011 (Bolton-Mags and Cohen, 2012). They represent a very small proportion of the total injections of anti-D Ig that are administered. There are no statistics available to tell us how much anti-D Ig is administered each year, however it is possible to estimate numbers.

Based on a UK birth rate of around ***800,000*** births per year, approximately ***128,000*** (16%) women will be RhD negative:

- All ***128,000*** will be offered RAADP (at least one, possibly two doses)
- ***76,800*** (60%) will also be offered postnatal anti-D Ig (those who deliver an RhD positive baby)
- Therefore at least ***204,800*** doses of anti-D Ig will be offered.

This does not take into account anti-D Ig given during pregnancy for a potentially sensitising event or additional anti-D Ig given at maternity units where a two dose

regimen is in place. Nor does it take into account those women who decline anti-D Ig, thought to be a small number. Given this it can be assumed that in excess of 205,000 doses of anti-D Ig are administered in the UK each year, giving an error rate (based on the most recent, 2011, SHOT annual report) that is almost certainly less than 1 in every 823 doses, or 0.1%.

It is difficult to know what error rate should be expected. Nemeth and Wessell (2010) report a prescription error rate of between 0.3% and 39% depending on their audit inclusion criteria. The SHOT annual report acknowledges that not all errors are reported (Taylor et al, 2009), and the research presented in Chapter six, analysis of anti-D Ig errors, suggests that some anti-D Ig errors may be underreported. In particular omission of anti-D Ig, where stock is held in clinical areas out with laboratory control, may be susceptible to going unrecognised. The SHOT annual reports find that the most common type of anti-D Ig errors are inappropriate and late administration of anti-D Ig (Bolton-Mags and Cohen, 2012). McSweeney et al (1998), following retrospective case note review, suggest that the most common failures are omission of anti-D Ig and failure to perform Kleihauer test. The SHOT analysis research, Chapter six, also suggests that omission of anti-D Ig may be underreported and highlighted situations where there is shared care and it is not always clear who is responsible for offering and administering anti-D Ig. Although the midwives in the focus groups felt very strongly that they and their colleagues would always report any error that they recognised, and the mechanisms appear to be in place to allow this, if there is no awareness that an error has been made it is impossible to report it.

Failure to recognise erroneous omission of anti-D Ig would appear to be the most likely category of underreporting. This is of particular concern as this is the error that is most likely to lead to maternal sensitisation and subsequently morbidity and mortality as a consequence of haemolytic disease of the fetus and newborn (HDFN). The potential for failure to recognise errors that may have important health consequences raises the question of whether maternity units should perform regular audit of care to determine whether anti-D Ig has been given appropriately. The

NICE (2008) RAADP guidance recommends that maternity units should perform regular audit to determine compliance with policy, although it is not clear how many maternity units do this. Regular and routine audit of RAADP policy is to be welcomed however this does not address errors that involve anti-D Ig given following potentially sensitising event or after delivery of an RhD positive baby. This research adds evidence to support the theory that omission of anti-D Ig is under reported and that organisations could do more to uncover this type of error. This holds particular clinical significance given the potential for omission of anti-D Ig to lead to morbidity and mortality due to HDFN.

8.3.2 Anti-D Ig and woman centered care

The most significant finding from the focus group research was that the midwives felt compelled to closely follow local policy and procedures. This was at the heart of their practice when providing care for women with an RhD negative blood type, and appeared at times to be at the expense of provision of woman centered, individualised care.

The concept of woman centered care, taking into consideration a woman's particular situation and needs and providing them with choice and control, has been central to maternity care policy in the UK since the publication in 1993 of the 'Changing Childbirth' report (Department of Health, 1993). The concept of patient centered care is now an established aspect of wider UK healthcare policy with Lord Darzi reporting that "care should be safe, effective and person centred" (Darzi, 2008, Pg8/9). Current Scottish policy such as the Refreshed Framework for Maternity Care (Maternity Services Action Group, 2011) reiterates its continued importance at government level NHS policy. Individualised, person centred, care is regarded as key to provision of quality care and, in maternity services in particular, as key to addressing lifelong health inequalities.

The establishment of clinical governance as a statutory duty for UK health organisations in 1998 was accompanied by the creation of organisations such as the National Institute for Clinical Excellence (NICE). This had the aim of supporting the

principles of evidence based practice and reducing variations in care across the UK. It has been noted that the concept of evidence-based care, which determines the best option from a population perspective, fundamentally conflicts with provision of person centred care (Karwalish, Fox and Pearlman, 2002).

The emphasis on policy and procedure rather than provision of individualised care pervaded through a number of themes within the focus group findings. These included the direct delivery of care, with an unwillingness to deviate from procedure for fear of being held accountable, to failure to engage with women due to lack of knowledge and understanding of the issues affecting their care. Willis (2001), cited by Watson (2004, Pg41), considers that within the context of professional accountability evidence based medicine can go wrong when "it stops being a tool and starts to become a master". That would appear to be the case here and the findings reflect failures at individual level to recognise and understand the scope of professional responsibility and the importance of person centred care in this aspect of practice. The findings also demonstrate the impact that organisation of care and organisational decision making with regard to policy and procedure have on midwives' ability to provide person centred care. The organisations within which midwives worked appeared to convey a strong sense of obligation to provide care within the framework of clinical governance. This was reflected by the midwives' equally strong sense that they would be held accountable should care deviate from local policy or were procedures not followed. In relation to the care of women with an RhD negative blood type, this resulted in failure to consider other aspects of quality care that could be achieved by using a person centred focus.

Again it is important to note that the focus groups represent only a very small number of midwives, however it is also of note that the findings from separate maternity units reported broadly similar views. The observation that the midwives' were intent on policy and procedure is an important finding and it highlights their failure to engage with women to provide individual care. An important aspect of provision of individual care is facilitation of informed decision making. This research has some important findings concerning the facilitation of informed

decision making in relation to anti-D Ig. It is of note that both the NICE (2002) and RCOG (1998) recommendations for RAADP contained a strong statements reiterating the importance of informed decision making and of encouraging women to make a choice about whether RAADP was right for them. The NICE (2002) guidance also included a list of the situations where a woman might decline RAADP such as when she was certain that the father of her baby was also RhD negative. However this research as a whole found that factors that might have supported midwives in delivery of that aspect of the guidance, such as education and written information, were of variable quality. The focus group interviews in particular found that the midwives who participated did not engage in in-depth discussion with women in order to facilitate choice about anti- D Ig.

The findings of the RAADP survey shed light on two aspects of implementation that influence informed decision making in practice: provision of education or training for staff, and provision of written information for women. The survey found that the majority of maternity units did provide education for staff at the time of implementation of RAADP, but within the limitations of the brief questionnaire used it was not possible to explore what form that took. The focus group research supported the survey finding that maternity units provided education around the time that policy was changed, however the midwives reported that this had been a policy update, with limited or no information or discussion about the background and evidence base behind the new guidance. The midwives also reported that not all of them had been able to attend face to face sessions, instead receiving written information about the changes. These findings suggest that although the maternity units met their obligation to disseminate policy changes reflecting the new guidance, they did not go as far as to provide education that would enable midwives to engage with women in order to meet the recommendations concerning informed decision making.

Watson (2004) suggests that instead of providing constraining frameworks for practice, we should educate practitioners properly to enable them to make decisions about care. The midwives who participated in the focus groups demonstrated a lack

of fundamental knowledge and understanding that would allow them to make decisions about care. A number of authors have suggested that healthcare professional's knowledge about anti-D Ig is poor, and that this may contribute to failures in care (Wray, 2000, Wickham, 1999b, Van Dijk, 1997). However this represents informed speculation and no formal evidence exists concerning healthcare professional's knowledge and understanding about anti-D Ig or the other issues that impact care offered to pregnant and parturient women with an RhD negative blood type. The focus group research undertaken here did find that the midwives who participated appeared to have good knowledge of the local policies and procedures that directly related to their practice, but that they had poor knowledge and understanding of other factors that impacted care. In particular they demonstrated poor knowledge of the risks and benefits of anti-D Ig and of the wider evidence that informed the recommendation to offer RAADP.

Midwives have a professional responsibility to understand the care that they provide (NMC, 2008). In order to provide safe and effective care they need to know policy and protocols, but they should also understand the rationale for their actions and be able to explain the care that they offer to women. However, it is of note that the midwives themselves did not see the need to receive education beyond dissemination of policy changes. They saw their accountability as being directly linked to providing care in line with the policies and procedures laid out by their employing organisation, rather than understanding wider accountability in relation to the women in their care. It is also important to consider that in this situation it may be that the midwives did not appreciate the need for further education because they did not have the knowledge to allow them to understand why that might be relevant to their practice. The focus group research was unable to explore this further, however it would appear that there was failure at managerial, organisational and individual midwife level to appreciate the scope and implications that implementation of the NICE guidance for RAADP held.

Perhaps unsurprisingly, given their apparent lack of understanding, the research also highlighted midwives dependence on written information. The focus group

interviews found that the midwives were very dependent on written information, both to support their own knowledge and to provide information to pregnant women. The midwives reported having limited discussion with women outside of presenting the information within the leaflets. The information they provided for women was that available within the organisations that they worked for. There is evidence that women like written information but that they also want an opportunity for face to face discussion. (O'Connor et al, 2007), and O'Cathain et al (2004) concludes that although patient information leaflets may help facilitate informed choice, they cannot deliver it when used alone.

The RAADP survey, Chapter five, found widespread provision of written information for pregnant women (at 97% of maternity units). However it also found a wide variety of leaflets, many of which had been produced by the maternity units themselves. The research did not include formal evaluation of factors that might impact on quality, such as readability, but content analysis showed significant variation, with several missing key information. This reflects the small study of information leaflets, aimed at RhD negative women, reported by Wickham (2007). Wickham (2007) questioned the quality and impartiality of the leaflets, finding that the majority did not mention side effects of anti-D Ig or present it as a choice. The RAADP survey, Chapter five, found that many maternity units produced their own leaflets about anti-D Ig. Although it is unclear why they should do so when NICE produced one to support implementation of the RAADP guidance, it has been suggested that some healthcare professionals choose to omit information that they think may cause anxiety (Oliver et al, 1999). Others suggest that when a choice being offered is policy, that it may be presented in such a way that they are not presented as choices at all (Davis, 2003). The midwives' dependence on written information and failure to engage in detailed discussion with the women, leads to concern about how women are able to make decisions about anti-D Ig. Although there is very little published evidence about this, several authors have questioned whether anti-D Ig is presented as a choice, and what exactly women understand about it (Wray, 2000,

Stewart, 1999, Wickham, 1999a, Wickham, 1999b), and others even question whether women know it is a blood product (Saha, 1998, Wickham, 2001).

The analysis of leaflets during the RAADP survey supports previous evidence in that the written information was most likely to omit details that might influence a woman's decision not to have anti-D Ig. The midwives within the focus group research also reported that they avoided discussing risks. During the focus group interviews, Chapter seven, the midwives described a process of documenting consent, rather than facilitating choice through discussion with the women. Midwives' failure to engage with the women was also evident in the SHOT analysis research, Chapter six. The SHOT research highlighted a number of situations where including the woman in the process of offering and administrating anti-D Ig might have prevented an error. For example a significant proportion of the errors involved inappropriate administration of anti-D Ig, most often to an RhD positive woman. Situations such as this raise the question of what these women were told about why they needed anti-D Ig and what they understood about their care. Interestingly during the focus group interviews the midwives described a consenting process for RAADP, but did not appear to see a need for further discussion with women when they required anti-D Ig later in their pregnancy or following delivery.

Some authors have questioned the appropriateness and achievability of informed decision making in today's healthcare system (Davies 2005) but there is a wealth of midwifery research to support the use of informed decision making to empower women and improve the quality of the care they receive. Evidence suggests that midwives regard informed decision making as an important aspect of their job (Levy, 2006) however this research found that the midwives here appeared instead to follow a consenting process that focussed on documenting the woman's decision. This happened in place of, rather than alongside, engaging women in discussion and encouraging them to consider choice in relation to individual circumstances.

Much of the research about informed decision making in maternity care concerns choice about issues such as place of birth and pain relief during labour. These issues

are entrenched in midwifery practice and are the type of choices that are considered integral to being a midwife. Although it is now a routine aspect of midwifery care, administration of anti-D Ig is in effect a medical intervention to prevent a complication of pregnancy. It may be that this has influenced midwives attitudes towards provision of choice around it and may help explain why they have not pursued acquisition of knowledge that might enable them to challenge aspects of policy such as provision of routine paternal testing, or to provide informed choice for women. Kirkham (2004) suggests that when a policy is routine there is risk of 'informed compliance' rather than informed choice. This may be particularly true if that policy originates within medical rather than midwifery practice.

8.3.3 Anti-D Ig and the midwifery profession

When a policy of RAADP was first called for in the UK (RCOG, 1998), it was met with strong resistance from midwives who challenged blanket intervention and called for a focus on improving existing care (RCM, 1999). This was based on substantial evidence that compliance with the then current guidelines was suboptimal and contributed significantly to on-going maternal sensitisation (Vause, Wray and Bailie, 2000, Howard et al, 1997, Ghosh and Murphy, 1994).

Rooks (1999) sums up the difference in approaches of the medical and midwifery professions, stating that:

> "Medical management often calls for applying treatments as preventative measures. The midwifery model recommends waiting until there is evidence that the intervention is needed".
>
> Rooks (1999, Pg 373)

The stance by the midwifery profession demonstrated this difference in approach to care, with midwives concerned about introduction of a routine intervention based on a population perspective rather than on individual need. The RCM called for the policy of RAADP to be reviewed by the National Institute for Clinical Excellence (NICE), stating that they would support it should NICE subsequently recommend this (RCM, 1999). However, the NICE review was a technology appraisal and as

such considered the intervention from a clinical effectiveness and cost effectiveness perspective and there was no new scientific evidence available for inclusion than that previously presented in the consensus statement (RCOG, 1998). It is of note that of the 26 members of the Appraisal Committee who conducted the guidance review in 2008 none were midwives (NICE, 2008).

The findings of this research highlight the potential for reduced quality of care that stems from lack of engagement with and by the midwifery profession during the development and implementation of policy. As the staff group who administer the majority of anti-D Ig, midwives were in a position to understand how scrutiny of midwifery practice could contribute to improving compliance with current guidelines. Similarly facilitating woman centred care that would enhance decisions based on an individual's situation, such as supporting paternal blood type testing, is an area of midwifery rather than medical expertise. Midwives could have made valuable contribution to formation of RAADP guidance and policy however, although the RCM called for exploration of such approaches, evidence in a form that would have been considered by NICE was not available for inclusion in the review.

Midwifery remains a developing profession, in 1986 the United Kingdom Central Council for nursing, midwifery and health visiting (UKCC) launched 'Project 2000' (UKCC, 1986) transferring all nursing and midwifery professional education to the university setting. This coupled with the more recent establishment of Professors of midwifery and Consultant midwife posts further enhance the status of the profession (Yuill, 2012). Midwifery research is also a developing field, and formal midwifery evidence on care provided for pregnant women with an RhD negative blood type remains extremely limited. Although this area of practice may be considered medical in origin midwives are the key care givers, and this thesis highlights the potential for improved care were the midwifery profession to engage on an equal standing with policy makers and contribute formal evidence to inform practice.

It is important to note however, that NICE chose to consider RAADP in isolation from other aspects of care that impact on pregnant and parturient women with an

RhD negative blood type, including when anti-D Ig is offered for other indications. In doing so the appraisal did not consider alternative approaches that had been suggested by midwives, such as the potential for reducing maternal sensitisation through improving current care. Although the midwifery profession failed to engage with policy makers at a level where they could effectively contribute to the NICE review the decision by NICE to conduct a Technology Appraisal, rather than produce more wide ranging clinical guidance, limited the contribution that midwives could make.

This research also uncovered failure at organisational level to implement the recommendations in a way that would meet the expectations of the midwifery profession to provide informed choice and woman focused care in relation to RAADP (RCM, 1999). The focus group research found that midwives' sense of responsibility to deliver care was closely linked their accountability to provide care in line with employer's policies and procedures. The organisations within which they worked fostered this culture through the way that care was organised and support, through provision of education and information, provided for the midwives. With both individual midwives and the wider organisations within which they work having written policy and procedure as a primary driver for provision of care, the wider objective of enhancing knowledge and understanding to support quality care and enabling staff to make decisions and to provide information to women was lost. This again reflects the opinion of Watson (2004) who suggests that clinical governance has seen an erosion of professionalism through the reduction of ability to exercise professional or personal accountability. It also echoes Kirkham (1999) who describes a culture of maternity services within the NHS in England which makes it difficult for midwives to practice within a woman centred approach to care. Kirkham (1999) states that

> "Midwives who are expected to facilitate choice and control for clients often lack professional experience of such facilitation, exercise little choice and control in their work and mistrust management".
>
> Kirkham (1999, Pg 737)

Watson (2004) argues that the only way that individualised care can be provided is through professional and personal accountability, but to do this midwives must have knowledge and understanding that gives them confidence to offer and facilitate choices that do not reflect policy. The midwives who participated in the focus group research neither had, nor recognised a need for, knowledge and understanding of the issues that influenced policy and failed to appreciate the scope of informed decision making for women with an RhD negative blood type. When describing clinical governance, Scally and Donaldson (1998) state that

> "NHS organisations are accountable for continuously improving the quality of their services… by creating an environment in which excellence in clinical care will flourish"
>
> Scally and Donaldson (1998, Pg 62).

While clinical governance has as its intention the provision of quality care, Watson (2004) argues that it is in fact a threat to professionalism through making clinicians accountable to a pre-determined framework rather than their own practice.

Although culture and practice at organisational level may be regarded as influencing individual midwives ability to provide quality care, it is important to acknowledge that organisations, in this case NHS Scotland and individual maternity units, employ members of the midwifery profession in senior positions from which they are able to influence policy and practice. Although midwives may have embraced the provision of choice for those issues that are deemed 'midwifery practice' such as place of birth and pain relief during labour, the changing face of maternity care in the UK means that most midwives are now regularly required to provide care that has its roots in the medical profession. Mason (2000) states that

> "Earlier aspirations of midwifery led maternity services in the UK have been shattered by the increasing incidence of medical interventions as routine procedures in normal birth, and by managerial policies designed to turn midwives into functionally competent 'service agents.''
>
> Mason (2000, web page)

However, it can be argued that it is within the power of the midwifery profession to regain control and influence over many of the 'medical interventions' that midwives now provide within the scope of routine maternity care. If midwives accept these interventions as part of their practice, they should also accept the challenge of providing them within the context of an evidence-based and woman focussed approach. It is vital that the midwifery profession engages with the development and implementation of such policies and that midwives at an individual level understand what they are offering and why.

This research demonstrates that even when an intervention originates in medical practice midwifery input is valuable, relevant and has great potential to positively influence care.

8.4 Limitations of research

Each of the individual research studies had limitations. These were described in Chapters five, six and seven and have been mentioned again in context of discussion of specific findings. However, it is important to restate here the major limitations of each of the separate pieces of research.

The RAADP survey questionnaire was intentionally short and simple. This approach was considered to be a significant factor in achieving the very high response rate, however it did limit the scope of the questions asked and meant that it could not explore issues in a way that might have added meaning to the results. The intention of this survey was to gain straight forward information about specific aspects of current policy and practice. The findings of the RAADP survey provided this and the additional questions it raised were addressed during the subsequent research presented in Chapters six and seven.

A significant limitation of the research presented in Chapter six, analysis of anti-D Ig errors reported to SHOT, was the lack of control over the data collection. The error reports came from across the UK, each being made by a different person. As such they are accounts by unknown people with unknown biases, unknown involvement

in the error, and using unknown methodology for investigation and reaching conclusions about what happened. Despite this significant limitation it was considered that the data was unique, important and meaningful. A major strength being that the error reports that were available for analysis represent all recognised errors involving anti-D Ig in the UK that were reported to SHOT over a twelve month period. The incidents reflect real situations and events, and despite the limitations of the work they provide a unique insight to actual clinical practice in this area.

A number of factors limit the scope of the focus group research. Conducting research that involves clinical staff in the NHS is always a challenge, and never more so than at a time where political and financial factors were imposing significant resource implications for maternity services in Scotland. Those constraints directly influenced the methods used here and, coupled with the resource limitations of this project, required the researcher to adopt a flexible and pragmatic approach to data collection. In practice this meant working with the midwifery managers and potential participants to find a way of holding the focus group interviews that would allow meaningful data collection within the serious constraints on time, availability and resources. Each session was allocated just one hour, and this meant that the moderator had to stick fairly rigidly to the topic guide and was not always able to explore ideas and areas of discussion that arose during the sessions in as much detail as she would have liked to. By adapting the methodology to a more structured approach than a traditional focus group, this was mitigated to an extent, however the data was limited both by lack of control over exactly who participated in the sessions and the need to cover a number of topics within the limited amount of time allocated.

A significant limitation of the focus group research was the small number of midwives who participated. Just eleven midwives in total, working at two of Scotland's seventeen maternity units. It is of note that the midwives who participated in the group interviews were very experienced, all having trained prior to 2002 when RAADP was first recommended. This gave them a particular perspective on the care

they offered and may have influenced their knowledge and attitudes, most specifically in relation to the lack of perceived benefit associated with RAADP.

Kitzinger (1995) describes the potential for the focus group setting to inhibit some participants from contributing fully. This did not appear to happen here and the midwives were at times quite open about not knowing or understanding issues. However, it is acknowledged that the group dynamic did influence the findings of this research. This was particularly true of the second group, group B. In group B the participants comprised one midwife who worked in an RAADP clinic and three community midwives who did not usually administer anti-D Ig. During the session the community midwives deferred to the specialist midwife's knowledge of some of the issues discussed and as a result a disproportionate amount of the data collected from this session came from this midwife. The community midwives did make a significant contribution on a number of the issues covered, but clearly the structure of this group impacted on the findings and further limited their application to a wider population.

However, the purpose of this research was not to generate findings that could be applied to a wider population, but rather it was to collect information to support and expand on the findings of the previous two pieces of research. The data collected was limited by the participants and by the time available for exploration of topics however the information and findings do reflect themes identified in published evidence and in SHOT reports and add an important and interesting perspective to the data collected through the other methods employed within this thesis. The limitations of the research are taken into account in interpretation of the findings.

When considered as whole piece of work the thesis has further limitations. The work was conducted over a number of years and practice and attitudes may have changed over that period of time, impacting on how the individual pieces of research relate and are relevant to each other. In addition although the SHOT research, Chapter six, and RAADP survey, Chapter five, are UK wide, the focus groups took place in two Scottish maternity units. Although organisation of care differed in those units the

midwives were practising within the context of NHS Scotland and the policy and practices of that organisation, educational system and culture. This may differ from that in the rest of the UK and could have impacted how the focus group findings relate to the other two pieces of research.

The limitations of the study are important and should be taken into consideration when applying the findings however the work remains valuable and is relevant to midwives, maternity units and the wider NHS when considering the organisation and provision of care for pregnant women with an RhD negative blood type in the UK.

8.5 Questions for future research

The thesis raises a host of questions for future research, reflecting the lack of midwifery research in this area of practice. Some of the questions have already been discussed in the earlier Chapters relating to the individual pieces of research that make up this thesis, and elsewhere within this discussion. Further pertinent questions are outlined here.

A number of research questions arise from the fact that the RAADP survey was conducted a number of years ago, these include: What is the current state of RAADP policy implementation? Do the demonstrated variations in practice continue? Are maternity units still producing their own leaflets? Inevitable changes in policy, guidance updates and the significant change in financial climate with resultant impact on the NHS in the UK, mean that it is highly likely that practice will have changed. The RAADP survey provided important contemporaneous information and could be repeated to answer these questions. The question of what the perceived barriers and enablers to implementing RAADP policy was important at the time the original survey was conducted, however if all UK maternity units do now offer RAADP the question may have become irrelevant. It might be more useful to conduct research to determine organisation of care in relation to provision of RAADP, with a focus on describing the factors that support effective provision of care. The influence of initiatives such as RAADP clinics and systems to hold stock of anti-D Ig in clinical areas could also be explored further. Any such research should

consider the impact that organisation of care has on compliance with guidelines and the provision of woman centred care.

Further research concerning the use of paternal blood type testing is also warranted. There is currently no evidence to tell us about the experience of women, their partners or midwives who use routine paternal testing. Conducting research that gains opinions on how such a policy might impact on current practice and whether it is a practical and effective option would be an important addition to the body of evidence to support provision of woman centred care for RhD negative women and their partners.

The research raised a number of questions about midwives knowledge and understanding of the issues around anti-D Ig. In particular the focus group research found that the midwives lacked knowledge about the issues that underpin policy and that this impacted on their ability and willingness to facilitate informed decision making. Clearly this was a very limited sample of midwives and wider ranging research is required to determine what midwives know about anti-D Ig and care of RhD negative women and the implications this has for midwifery practice and provision of informed choice. This aspect of research might also consider midwives understanding of the scope of their responsibility and accountability in this area of practice. Potentially this research would have implications beyond care provided for RhD negative women, informing other aspects of practice where medical intervention has become routine midwifery practice.

8.6 Conclusion

This research produced original and important findings that provide valuable insight to the care that midwives provide for women with an RhD negative blood type.

The midwifery approach to care acknowledges the significance of women's individual differences and offers care based on specific needs and choices of a particular woman. Midwives recognise that involving women in their own care can have far reaching positive consequences for them and their families (Leap, 2009).

This contrasts significantly with the biomedical approach to care taken by scientists and medical staff in which care is often based on a population perspective. Policy and practice recommendation surrounding care for women with an RhD negative blood type is developed from a biomedical approach. As such it places great value on evidence gathered through large quantitative studies that informs biomedical outcomes, and little consideration is given to evidence of other types that may contribute to a wider view of quality care. This approach means that midwives have so far made very little contribution to the evidence base or policy formation in this area of practice. Importantly, although midwives provide the majority of direct clinical care in relation to anti-D Ig and the care of women with an RhD negative blood type, medical staff and scientists produce policy and most often dictate practice. This creates a conflict where midwives may be delivering care based on policy and practice that is contrary to their philosophy of care.

The research presented in this thesis represents the first time that this aspect of care has been considered from a midwifery perspective. The research findings are broad and provide a unique and valuable insight that encompasses National implementation of policy, provision of direct clinical care and individual midwives knowledge, understanding and views on key issues identified as impacting the quality of care.

Specifically, the findings of this research describe policy implementation at National level, highlighting widespread implementation but with significant local level variations. Those local level variations tend to be factors that impact on delivery of woman centred care by midwives, such as offering paternal blood group testing and provision of information about anti-D Ig. The findings also give insight to the errors involving anti-D Ig that are made by midwives, and for the first time provide a framework for examining procedures, documentation and organisation of care. This will allow midwives to examine and influence practice from their own perspective: providing a means for midwives themselves to scrutinise the care that they deliver, and to put in place measures to improve the quality of care provided for women with an RhD negative blood type.

The focus group research allowed consolidation of the previous findings and led to the development of unique and important insight to midwifery practice in this area. In particular the significant finding that midwives lacked knowledge and understanding of issues impacting provision of care beyond straight forward policy and procedure was found to influence the care they provided. The research also highlighted that midwives and the wider organisations that employed them were driven to provide care in line with policy and procedure, and that this had a negative impact on provision of woman centred care and informed decision making.

The research findings demonstrate the potential impact that greater midwifery engagement and involvement could have on policy and practice development, and on the quality of clinical care provided to women with an RhD negative blood type. They highlight specific measures that midwives can take to regain a midwifery perspective on this aspect of care, and are significant for individual midwives, the NHS organisations who employ them, professional bodies that represent midwives and for women with an RhD negative blood type.

The research as a whole raises important questions about how government objectives for individualised, woman centred care can be achieved within the framework of clinical governance and evidence based care that is also set out in National policy. It highlights the challenges that stem from midwives' roles and responsibilities within the current maternity care setting, which increasingly see them accept responsibility for care that originated within the medical profession. This raises questions about how the midwifery profession engages with medical colleagues and policy makers to establish a midwifery context and maintain quality care.

This research was focussed on provision of care for RhD negative pregnant women, however many of the issues raised are pertinent to other aspects of midwifery practice and the findings raise important questions about the organisation and culture of maternity services, and the midwifery profession, in relation to the role of medical and midwifery staff. Although this research has significant limitations, the thesis provides important, substantial and previously absent insight to the policy, practice,

and professional and organisational issues that impact the care provided for women with an RhD negative blood type by midwives.

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Appendices

Appendix 1: Transfusion Medicine Article (Harkness et al, 2008)

Transfusion Medicine, 2008, 18, 292–295 doi: 10.1111/j.1365-3148.2008.00882.x

SHORT COMMUNICATION

Implementation of NICE recommendation for a policy of routine antenatal anti-D prophylaxis: a survey of UK maternity units

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SUMMARY. The aim of this study was to determine how many UK maternity units have implemented National Institute for Clinical Excellence (NICE) guidance for routine antenatal anti-D prophylaxis (RAADP). In May 2002, the NICE recommended a policy of RAADP for RhD-negative pregnant women. The policy has the potential to reduce maternal sensitization and prevent deaths from haemolytic disease of the foetus and newborn, but implementation entails considerable clinical, financial and organizational challenges. A postal survey of all 324 UK maternity units was completed in 2005.Responses were received from 91% of units (294 of 324). RAADP was offered by 220 of 294 (75%) and in England and Wales 19% of those offered a single-dose regime. At 12% of maternity units, routine paternal blood group testing was offered. For 84% of maternity units, staff education was offered at the time of implementation. Written patient information was provided at 97% of maternity units and 147 of 217 (69%) returned a copy. We received 60 different leaflets. Three years after NICE guidance was issued, one in four maternity units did not offer RAADP. Among those that do offer RAADP, practice with regard to anti-D administration, paternal testing, provision of written information and staff education varied. Unit and clinician level research is required to understand why.

Key words: anti-D, guidance implementation, NICE, RAADP.

BACKGROUND

Approximately 16% of the UK population has an RhD-negative blood type, and in about 10% of all pregnancies, the mother is RhD negative and the foetus RhD positive. During these pregnancies, the mother is at risk of sensitization with anti-D antibodies. For more than 30 years, the UK has had in place a programme of anti-D prophylaxis following the birth of an RhD-positive baby and, more recently, following identification of a potentially sensitizing event during pregnancy. Despite this programme of prophylaxis, around 1% of RhD-negative pregnant women will still develop anti-D antibodies. The resulting haemolytic disease of the newborn (HDN) affects around 500 babies and causes 25–30 foetal or neonatal deaths each year within the UK [National Institute for Clinical Excellence (NICE), 2002] (population approximately 60 million).

In May 2002, the NICE made the recommendation that all pregnant women with an RhD-negative blood group should be offered routine antenatal anti-D prophylaxis (RAADP) at 28 and 34 weeks gestation. This guidance aims to reduce maternal sensitization from the current rate of 1% to around 0 35%, preventing around 17 late foetal or neonatal deaths due to HDN each year (NICE, 2002).

Both the Health Technology Board for Scotland (www.nhshealthquality.org.uk) and the Department for Health, Social Services and Public Safety (www.dhsspsni.gov.uk) in Northern Ireland endorsed the guidance making it a UK-wide recommendation.

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Implementing RAADP has significant financial, organizational and clinical implications at both national and local level and in 2002, when the NICE guidance was published, only an estimated 12–30% of UK maternity units offered RAADP (NICE, 2002). The aim of this study was to determine how many maternity units are currently complying with the guidance.

METHODS

A questionnaire was developed specifically for this survey and contained questions that were based on the NICE recommendations concerning administration of anti-D, information provided to RhD-negative women and staff education and training. To ascertain implementation of RAADP at local level, the survey targeted individual UK maternity units offering antenatal care, rather than trusts, divisions or health boards.

Questionnaires were posted to all 328 UK maternity units (identified via the Web site www.birthchoiceuk.com) in July 2005, each addressed to the senior midwife for antenatal care. The maternity units included private birth units, general practitioner- and/or midwife-led units, and larger maternity units at district general and teaching hospitals. After 6 weeks non-responders were sent a reminder with a further copy of the questionnaire.

The questionnaire included a request for a copy of any written patient information about RAADP. A basic analysis was performed of the origin and content of the leaflets returned. Origin was categorized as follows:

Commercial: produced by the manufacturers of anti-D immunoglobulin

National Health Service (NHS): produced by national NHS bodies such as NICE, National Blood Services (NBS) and Scottish National Blood Transfusion Service (SNBTS)

Local: produced by local NHS trusts, divisions or maternity units

Twelve key pieces of information were identified from the patient information issued with the NICE guidance. These are detailed in the Results (Table 1). The 'coverage' of each leaflet was ascertained by profiling it against these key facts, as covered or not (meaning a leaflet 'coverage score' can range between 1 and 12).

Data were entered into a spreadsheet by one researcher, checked and rechecked, and then analysed using the computer software package spss v13.

RESULTS

Replies from 4 of the 328 maternity units surveyed stated that antenatal care was no longer provided at that site. Of the remainder, 91% returned completed questionnaires (294 of 324).

Of all maternity units responding, 220 of 294 (75%) offered RAADP. In Northern Ireland, all 12 maternity units offer RAADP, in England and Wales this figure was 180 of 243 (74%) and in Scotland 28 of 39 (72%).

In England and Wales, a single-dose regime of RAADP is available as an alternative to the two-dose regime. This was offered by 35 of 180 (19%) of units offering RAADP.

Routine paternal blood group testing was offered by 27 of 220 (12%) of maternity units that offered RAADP though in Northern Ireland this was 11 of 12.

At 9% of units (20 of 220), implementation of RAADP had not been accompanied by staff education, whereas for another 9% (19 of 220) these data were missing. For the 84% of the 181 maternity units that did offer staff education at implementation, it took the form of group training sessions (in the majority of cases with provision of written information). Ongoing staff education was in place at 100 (45%) of the maternity units that offer RAADP, and this

Table 1. Key information used to measure content of patient information leaflets

Key information expected	Number (%) of leaflets that omitted the information
State circumstances in which RAADP is unnecessary	44/60 (73)
Indicate the actual incidence of HDN	43/60 (72)
Explain that if the father's blood type is also RhD negative then anti-D is not required	41/60 (68)
State that RAADP is recommended by NICE/NHS	35/60 (58)
Give sources of further information about RAADP: Web sites or phone numbers	33/60 (56)
State the likely risk of viral transmission via anti-D	12/60 (20)
Explain what HDN is	11/60 (18)
Explain potentially sensitizing events (PSE) and need for anti-D	10/60 (17)
State that anti-D is a human blood product	8/60 (13)
Offer further discussion with a midwife or doctor	8/60 (13)
Explain RAADP and how it differs from anti-D prophylaxis following a PSE	5/60 (8)
Explain why the problem occurs	4/60 (7)

was more likely to be in those with more recent introduction of RAADP. Of units offering RAADP, 214 of 220 (97%) provided written information about it for pregnant women and 147 of 214 (69%) returned copies of the information they provided, 30 sending two different leaflets and 6 sending three. Altogether there were 60 distinct leaflets, of which 8 were produced by commercial manufacturers of anti-D, 7 by national NHS bodies and 45 by local NHS trusts or maternity units. The most commonly used leaflets were firstly a commercial one (used by 35 maternity units) and second the NICE leaflet (26 units). Thirty-three leaflets were specific to a single maternity unit.

Analysis of content of the leaflets showed that omission of key information ranged across the recommended key points from 73 to 7% (Table 1). Only 3 of 60 (5%) contained all 12 key pieces of information, whereas 16 (27%) contained 6 or fewer key points, 3 containing just 3. The leaflets in use at maternity units where RAADP had been introduced prior to the 2002 NICE guidance were less comprehensive than those used by units where RAADP was introduced after guidance was issued (Mann Whitney U P ♦ 0 001; n ¼ 31, 105). For units returning more than one leaflet, this was regardless of whether the coverage score used in the analysis was that of the worst leaflet, of the best leaflet or of the combination of information across leaflets. Considering combined score, the percentage of units omitting five or more pieces of information was 39% among early adopters, 12% among the rest. Coverage did not vary markedly by size or type of unit.

DISCUSSION

This survey found that by July 2005 the majority of maternity units offered RAADP (75%), but as many as one in four were yet to implement the guidance. The study highlights local and regional variations in practice, education available about RAADP for clinicians and in the information provided to pregnant RhD-negative women.

The survey had a high response rate (91%), a major strength, and it also generated a large amount of correspondence, suggesting that RAADP was a subject of particular interest and relevance to the respondents.

Weaknesses of the study are those common to postal surveys: lack of control over who completes the questionnaire and potential inaccuracy in the information provided. The principal outcome, whether or not RAADP is offered, was straightforward and current, and hence likely to be accurate. However, some of the items, in particular those regarding the information and education offered at the time of implementation, may have been more difficult to answer, particularly in those maternity units that have offered RAADP for a number of years.

The survey questionnaire was intentionally short and simple. Although this approach may have boosted the response rate, it also means that the questions asked were limited and did not explore issues that could have added meaning to the results, such as perceived barriers to the implementation of RAADP.

Clinical guidelines have the potential to improve patient care, reduce the significant regional and local differences in available treatment and are recognized as a key method of disseminating best practice. However, there is evidence that implementation of NICE guidance has been patchy across the NHS (Sheldon et al., 2004). In May 2002, when NICE issued its recommendation for RAADP, it was estimated that between 12 and 30% of maternity units offered the intervention (NICE, 2002). We found that 3 years after the guidance was issued, one in four maternity units were still to implement the policy. We did not explore the reasons for this although it is clear that implementation of a programme of routine antenatal anti-D prophylaxis has clinical, financial and educational implications that require significant local-level multidisciplinary review of policies and practices.

Even among those units offering RAADP, we found some regional and local differences in implementation of the guidance. Although the NICE guidance states that RAADP should be given as two separate injections of 500 IU, given at 28 and then 34 weeks gestation, in England and Wales 19% of maternity units offering RAADP were giving a larger single dose at around 28 weeks gestation. Anecdotally, the number of units using the single dose is growing and this variation in practice has important clinical implications, in particular for those women who move between maternity units during a pregnancy. If clinicians are to offer all RhD-negative women the most appropriate care and advice, they need to be aware that practice may vary in other areas.

Another aspect of practice that varied was paternal blood type testing. Identifying the father's blood type as RhD negative could reduce costs and prevent unnecessary administration of anti-D, but there appears to be general reluctance towards doing this. Reasons often cited anecdotally include potential misidentification of the father and the extra administration involved in obtaining paternal samples. This is reflected by the fact that just 12% of maternity units routinely offer to test paternal blood type. The emerging possibility of testing foetal DNA from maternal blood samples may mean that paternal

testing becomes obsolete. However, until then, the experience of those maternity units that already offer routine paternal testing could provide valuable insight into the practicalities of offering this test.

The ability to appropriately administer anti-D in line with published guidance and to provide accurate and relevant information that enables informed decision making will depend on the clinician's knowledge and understanding of the issues involved. This survey explored two factors that influence clinician's ability to provide quality care: provision of written information about RAADP and the education they receive about RAADP.

For the majority of clinicians, information about RAADP will have been derived after their initial medical or midwifery training. Within the limitations of this survey, it is impossible to make any judgements about the quality of the education on RAADP that was offered. However, the majority (82%) of maternity units did offer staff education at the time of implementation of RAADP, although only 45% offered ongoing education. Interestingly, ongoing staff education was more likely to take place in the maternity units that had implemented RAADP more recently.

The widespread introduction of an intervention that will benefit few individuals, and which may carry some risks, makes it imperative that women are able to make an informed choice, based on accurate information (NICE, 2002). With the lengthening list of issues to discuss at antenatal appointments and the pressure on time available for appointments, clinicians are increasingly dependent on written patient information. NICE recommended that 'high quality information, validated and produced at the national level, must be made available to RhD-negative women' (NICE, 2002), and although the overwhelming majority of units did provide written information (97%), we do not know how reliably this is given to the women who need it. Furthermore, locally produced leaflets were being used by over a third (35%). We did not explore why so many maternity units chose to produce their own patient information leaflets, a time-consuming and expensive option. It suggests dissatisfaction with nationally produced material such as those produced by NICE and the NBS, but it is unlikely that expertise in written communication for patients was available to many of those producing 'local' leaflets. Although it is important that leaflets are easily understood, this should not be to the extent that key information is omitted. The comprehensiveness of the leaflets that were examined varied considerably and almost all omitted at least some of the key information. Interestingly, those implementing RAADP after NICE issued their guidance used more comprehensive leaflets (according to the 12 key pieces of information we identified). It may be that they were able to base the information they provided on the literature available from NICE and this may suggest that the NICE guidance has had a positive impact on the information available to patients, both written and through caregivers. However, it might also suggest that maternity units who introduced RAADP prior to 2002 have yet to review and update their information and staff training in light of the new guidance. This raises concerns regarding disparity in care provided by different maternity units and suggests a need for a coordinated national campaign to review the production and dissemination of high-quality information and care for RhD-negative pregnant women.

REFERENCES

NICE. (2002) Guidance on the Use of Routine Antenatal Anti-D Prophylaxis for RhD Negative Women. National Institute for Clinical Excellence Technology Appraisal Guidance No. 41. NICE, London.

Sheldon, T.A., Cullum, N., Dawson, D. et al. (2004) What's the evidence that NICE guidance has been implemented? Results from a national evaluation using time series analysis, audit of patients' notes, and interviews. British Medical Journal, 329, 999–1004.

Appendix 2: Correspondence from NICE reviewer

Scottish National Blood Transfusion Service
Aberdeen & North East Scotland
Blood Transfusion Centre
Forresterhill Road
Foresterhill
ABERDEEN, AB25 2ZW
Telephone 01224 685685
Fax: 01224 695351
www.snbts.org.uk (General Information)
www.scotblood.co.uk (Donor Information)

NHS
National
Services
Scotland

SJU/AST/NAIT/MHARKNESS

Enquiries to PROFESSOR SJ URBANIAK
E-mail stan.urbaniak@snbts.csa.scot.nhs.uk

15 October 2007

Main Harkness
SE Scotland Blood Transfusion Centre
Royal Infirmary
51 Little France Crescent
Old Dalkeith Road
EDINBURGH, EH16 4SU

Dear Main

UPDATE OF RAADP – NICE REVIEW 2008

Sorry that I did not have an opportunity to meet up with you at the BBTS, when I would have hoped to have a discussion with you about your poster.

You may know that NICE is undertaking its 5-year review of the previous advice given, and I have been asked to be one of the assessors in reviewing the evidence.

I would very much like to submit the information that you presented in your poster, as evidence of compliance to NICE, and wondered if you had an A4 version of your poster that could be used.

There may also be further questions of detail requested, and I hope that I can work with you to provide them with this information.

The key question I see at the moment is to identify the numbers of Rh-negative women not receiving RAADP, from within the overall statistics on non-participating maternity units.

If you can list the names of the maternity units, I can identify statistics on the numbers of RhD negative women treated from other sources, and come up with a reasonable estimate of the number of women not receiving RAADP at the time of your survey.

This information I think has important implications for calculations of cost effectiveness etc, and should be available to the respective policy makers.

Could you please let me know if you are willing and able to participate, so that I can inform the NICE review Committee?

Kind regards.
Yours sincerely

Professor SJ Urbaniak
National Advisor in Immunohaematology

cc: Prof IM Franklin

SNBTS Head Office
Ellen's Glen Road, EDINBURGH, EH17 7QT
National Director Keith Thompson
SNBTS is a Division of the Common Services Agency

Appendix 3: Letter from South East Scotland Research Ethics Service

South East Scotland Research Ethics Service

Deaconess House
148 Pleasance
Edinburgh
EH8 9RS
Tel: 0131 536 9067
Fax: 0131 536 9346

NHS Lothian

Name: Mairi Harkness
Address: Transfusion Specialist Midwife
BBT
SNBTS
Ellen's Glen Road
Edinburgh
EH17 7QT

Date: 07/06/2010
Your Ref:
Our Ref: NR/1005AB1
Enquiries to: Alex Bailey
Extension:
Direct Line: 0131 536 9050
Email: alex.bailey@nhslothian.scot.nhs.uk

Dear Mairi,

Full title of project: 'Examining anti-D errors: how can midwives be best supported to improve care?

You have sought advice from the South East Scotland Research Ethics Service on the above project. This has been considered by the Scientific Officer and you are advised that, based on the submitted documentation (Outline for alex bailey), it does not need NHS ethical review under the terms of the Governance Arrangements for Research Ethics Committees in the UK. The advice is based on the following:

- *The project is an opinion survey seeking the views of NHS staff on a healthcare issue.*

If this project is being conducted within NHS Lothian you should inform the relevant local Quality Improvement Team(s).

This letter should not be interpreted as giving a form of ethical approval or any endorsement of the project, but it may be provided to a journal or other body as evidence that ethical approval is not required under NHS research governance arrangements. However, if you, your sponsor/funder or any NHS organisation feels that the project should be managed as research and/or that ethical review by a NHS REC is essential, please write setting out your reasons and we will be pleased to consider further. Where NHS organisations have clarified that a project is not to be managed as research, the Research Governance Framework states that it should not be presented as research within the NHS.

You should retain a copy of this letter with your project file as evidence that you have sought advice from the South East Scotland Research Ethics Service.

Yours sincerely,

Alex Bailey
Scientific Officer
South East Scotland Research Ethics Service

Appendix 4: RAADP Survey Questionnaire

RAAP Survey

We are surveying every maternity unit in the UK about practice with regard to ***routine antenatal anti-D prophylaxis (RAAP)***. We request that one questionnaire is completed for each unit, by the senior midwife for antenatal care, or equivalent.

Please complete this questionnaire by placing a tick in the circle ✓

and/or by writing your answers in the space provided .....

1. **Name and designation of person completing this survey:**

.....

2. **Which of the following apply to your maternity unit?** *Please tick all that apply*

O Consultant led unit O Midwife led unit O GP Unit

O Other *(please specify)* .....

3. **Approximately how many babies are born in your unit each year?**

O 1-500 O 501-1500 O 1501-3000 O 3001+

4. **Please give an email address, or telephone number, to allow the researcher to contact you with any queries about your replies**

.....

.....

.....

5. **Would you like a copy of the results of this survey?**

O Yes O No

If yes, please ensure that your contact details, above (Q4), are complete and correct.

1

For the purposes of this questionnaire survey, **Routine Antenatal Anti-D Prophylaxis** is anti-D offered ***routinely***, during pregnancy, to women with an RhD negative blood type. For brevity this will be referred to as ***RAAP***.

6. **Does your maternity unit currently have a policy of <u>routine</u> antenatal anti-D prophylaxis (RAAP)?** *Please see definition in box above*

   O Yes O No

   IF YES please continue. IF NO please turn to the back page.

7. **Does your unit RAAP policy <u>exclude</u> any of the following women from the RAAP programme?**
   Please tick all who are excluded from RAAP. Please add any comments if you wish.

   O Women who will be sterilised following the birth of their baby
   O Women who know the father of their baby is RhD negative
   O Women who are certain that they will not have another baby
   O Women who already have a living child
   O Others *(please give details)* .....

8. **For those eligible for RAAP, at what gestation is the first injection of routine anti-D offered?**

   ☐ weeks

9. **For those eligible for RAAP, is a second injection offered?**

   O Yes O No

   If Yes, at what gestation is it offered? ☐ weeks

10. **Does your unit <u>routinely</u> offer every pregnant RhD negative woman an opportunity to have her partner's blood type tested?**

    O Yes O No

11. **Does your unit provide <u>written</u> information about RAAP for RhD negative pregnant women?**

    O Yes, for all RhD negative women
    O Yes, but only for those who will be offered RAAP
    O No written information provided

If yes, please include a copy of this information when you return our questionnaire.

12. From what date was RAAP first introduced in your Unit?

☐ Month ☐ Year

13. Was the introduction of RAAP accompanied by specific education for clinical staff?

O Yes O No O Don't recall

If yes, what did this comprise? *Please tick all that apply*

O Provision of written information
O Group training/teaching sessions
O Other (please give details).....

Who was offered this education? *Please tick all that apply*

O Midwives
O Junior medical staff
O Senior medical staff
O Others (please give details).....

14. Do you *currently* offer ongoing RAAP education for clinical staff?

O Yes O No O Don't know

If yes, what does this comprise?
Please tick all that apply

O Provision of written information
O Group training/teaching sessions
O Other (please give details).....

15. Who is offered ongoing education about RAAP?
Please tick all that apply

O Midwives
O Junior medical staff
O Senior medical staff
O Others (please give details).....

Thank you very much for completing this questionnaire. Please return it in the enclosed envelope.

PLEASE ALSO REMEMBER TO ENCLOSE A COPY OF ANY WRITTEN INFORMATION YOU PROVIDE FOR WOMEN ABOUT RAAP.

If your envelope is missing, the completed questionnaire can be returned to:

Mairi Harkness,
EUB Office,
SNBTS,
Ellen's Glen Road,
Edinburgh, EH17 7QT

If you prefer to have another envelope sent out please:

email mairi.harkness@snbts.csa.scot.nhs.uk or telephone (0131) 536 5962

Study site code

Appendix 5: Focus Groups Topic Guide

Openers/Information:

Purpose and format of the session –PhD research, to find out more about what midwives think and how they practice.

Success depends on good discussion with each other -hope they can feel open and honest, and that individual opinions and experiences will be respected now and in workplace going forward.

Will tape record the session so that I can analyse the data –can't take notes quickly enough.

Completely anonymous, no-one will be named or identified in any way.

I won't answer questions during the session but will have an opportunity to do so afterwards.

Scenario 1, Mary.

"You are working as a community midwife.

Mary, a 23year old p2+0, has complex social problems and a history of poor attendance at antenatal appointments.

At 28 weeks Mary attends your antenatal clinic without an appointment. You go ahead with her check, during which she tells you that she has a negative blood type.

Mary does not have her hand held notes with her, there is no GP in the surgery and you are unable to contact BTS to confirm her blood type. You know that Mary is unlikely to attend the clinic again in the next few weeks."

Open a general discussion about what they would do.

In particular:
What are the risks of giving her anti-D if she is in fact RhD positive?
What are the risks of her not receiving RAADP?
Can you justify, in terms of professional accountability, giving anti-D without knowing her blood group?
Do any other factors influence the decision you make?
If choose not to give anti-D why not? (risk to woman? Or risk to midwife?)

Questions:

What is anti-D?
Midwives attitudes towards it -Is it safe, are they OK with giving it? Do some midwives avoid it?

Exercise/Scenario: Diane

"You are working as a midwife on a busy postnatal ward.

The duty FY2 tells you that Diane, a p1 who had a caesarean section last night, requires anti-D. The doctor writes a prescription and asks you to give the anti-D from ward stock.

Write your actions on post-it notes, step by step, up to the point you give anti-D".

Steps: Who would you speak to, if anyone?
What would you check if anything?
What/where do you document, if anything?

Who is responsible for the error?

Which of the following checks are important/regularly done in this situation? (On card)

Questions:

Have they heard of SHOT?
Who reports errors and to where?
Do they think it's important to report errors?
Do people always report errors? If not, why not?

Scenario 2, Kim

"Kim, who has blood type A negative, has an SVD at 7pm and is discharged home the following morning.

That afternoon, anti-D for Kim arrives on the ward and is placed in the fridge.

When the community midwife discharges Kim on Day 10, she notices that she should have received anti-d but did not. The ward check and find the anti-D still in the fridge."

Who is responsible?
What could have been done differently?
How does documentation influence whether anti-D is given when it should be?
Could the system be improved to avoid this type of situation?

Is there a formal way of checking whether anti-D has been omitted? – how is this audited?
Is communication between community and hospital good?
How is need for anti-D highlighted? Documentation antenatally? Discharge checklists, is there something pre 72hours postnatal to remind midwives?

What ways can you check a woman's blood group?

Questions:

What formal teaching have you had, in relation to anti-D, since qualifying as a midwife?

Is poor understanding a problem?

Who do you ask if you don't know what to do, or what a result means?